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# **Dräger** medical

A Dräger and Siemens Company

# Field Service Procedure

Part Number: SP00181

Rev: L

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Narkomed 6000 Series PMC Procedure

NM6000 Series PMC PROCEDURE

#### 6.0 PMC PROCEDURE, NARKOMED 6000 SERIES

The procedures in this section shall be performed in their entirety at initial installation, then as specified, during all scheduled Periodic Manufacturer's Certification (PMC) visits, and each time a component is removed, replaced, calibrated or adjusted. The exception to this requirement is the Integrated Patient Monitoring Module, (IPMM) and/or Gas Analyzer Pod 2, (GAP2) installed on the Narkomed 6400. The Narkomed 6400 has been specifically designed to operate these assemblies as plug and play devices in the event of a failure during clinical use. Draeger Medical, Inc. recommends the following precautions:

- Spare GAP-2 and/or IPM pods should be controlled carefully by the facility.
- Before replacing the GAP-2 and/or IPM pod, the clinician should verify that the replacement pod appears to be in good condition. If there is any doubt about the replacement pod's quality, the pod should not be used without first contacting an authorized representative of DraegerService.
- The clinician should perform a complete Narkomed 6000 Series selftest as soon as practical. Full system self-diagnostics will run at that time.

Follow the testing interval during all scheduled Periodic Manufacturer's Certification (PMC) visits. A Narkomed 6000 Series PMC Checklist form, P/N 4115093, is available from Draeger Medical, Inc. and shall be completed by the Technical Service Representative each time a PMC is performed. If the machine is equipped with an Integrated Patient Monitor (IPM) or strip chart recorder, the technician shall also complete an IPM and Strip Chart Recorder checklist form, P/N 4116820. The section numbers on the PMC checklist form are keyed to paragraph numbers in this manual. Steps in the procedure marked with (✓) require a response at the corresponding line on the checklist form.

Space is also provided on the PMC Checklist form to record the results of a vapor concentration test. Refer to the current Anesthesia Equipment & Monitoring System Service Information CD-ROM Service Procedures section for vapor concentration verification procedures.

NOTE: Test equipment listed below with an asterisk (\*) requires calibration at a maximum interval of one year. Verify the dates on test equipment calibration labels. DO NOT USE any test equipment having an expired calibration date. Notify your supervisor immediately if any equipment is found to be out of calibration.

In the space provided at the bottom of the PMC checklist form, record the Model and ID number of all calibrated test equipment used.

## Base Machine Test Equipment Required:

NOTE: If the machine is equipped with an IPM and/or strip chart recorder, refer to Section 6A in this manual.

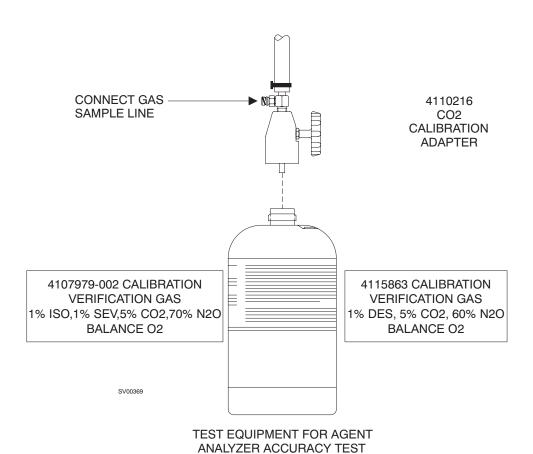
- -- \*Electrical Safety Analyzer (Biotek 501 Pro or equivalent)
- -- AC Receptacle Tester (IDEAL 61-035 Circuit Tester or equivalent)
- -- \*Test Pressure Gauge, P/N 4114807 or equivalent
- -- \*Flowmeter Test Stand (Capnomed), P/N S000081 or equiv. w/5% FS accuracy

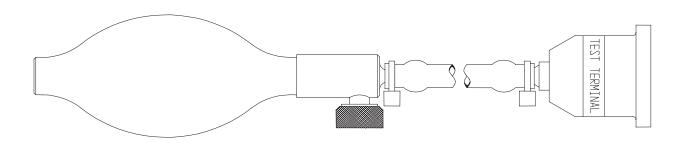
- -- \*Test Minute Volume Meter, P/N 2212300 or equivalent
- -- \*Digital Pressure Manometer (SenSym PDM 200CD or equivalent)
- -- \*Riken Gas Indicator, Model 18H, or 1802D or equivalent
- -- Stop Watch
- -- Test Lung, Siemens P/N 8401892

### Base Machine Materials Required:

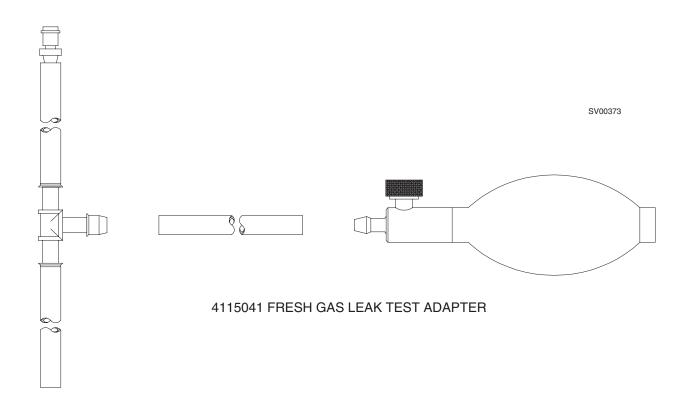
- -- Rubber goods set: Y-piece, elbow, 2x 32" x 22mm hoses, 2L bag P/N 1101071
- -- Tube, corrugated, 22 mm x 32 in. long, P/N 9995132
- -- Adapter assembly, test terminal, P/N 4104389 or equivalent: two are required
- -- Adapter, CO<sub>2</sub> calibration, P/N 4110216
- -- Adapter, fresh gas leak test P/N 4115041
- -- Adapter, GAP return P/N 4115040
- -- Adapter, suction pipeline P/N 4115039
- -- Molykote 55M grease P/N 4115127
- -- Cylinder, calibration gas 1% DES, 5% CO<sub>2</sub>, 60% N<sub>2</sub>O, Bal O<sub>2</sub> P/N 4115863
- -- Cylinder, calibration gas 1% ISO, 1% SEV, 5% CO $_2$ , 70%  $\rm N_2O$ , Bal $\rm O_2$  P/N 4107979-002
- -- Adapter, volumeter/freshgas hose P/N 4115042
- -- Adapter, PDM to patient suction P/N 4115038
- -- Adapter, connectors 33mm x 22mm P/N 4115087
- -- Qdisc, male fresh gas P/N M31581
- -- Tube, PVC sample line P/N 4108103
- -- Breathing sys leak test device P/N S010159
- -- Adapter, PDM to monitor P/N 4115043
- -- Fitting, Luer lock (F) x c MPT P/N 4110709
- -- Pipet, disposable P/N 4115090
- -- Silicon Rubber, Walker Elastosil, E41g, 90 ml P/N 1202537
- -- Static Field Service Kit, P/N S000095
- -- Kit, PMS NM6000, 6 month P/N 4115074-001
- -- Kit, PMS NM6000, 1 year P/N 4115074-002
- -- Kit, PMS NM6000, 2 year P/N 4115074-003
- -- Kit, PMS NM6000, 3 year P/N 4115074-004
- -- Kit, PMS NM6400, 6 month P/N 4118084
- -- Kit, PMS NM6400, 1 year P/N 4118085
- -- Kit, PMS NM6400, 2 year P/N 4118086
- -- Kit, PMS NM6400, 3 year P/N 4118087

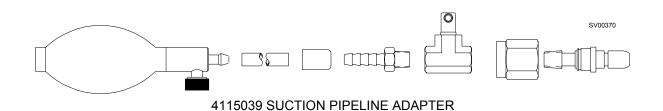
Special test fixtures are illustrated on following pages.

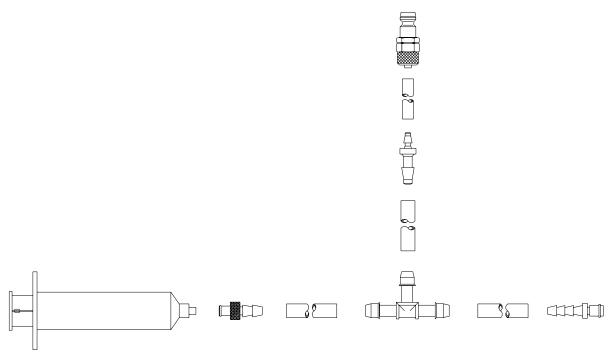




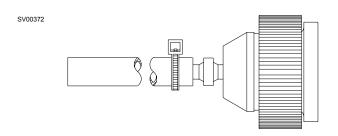
S010159 BREATHING SYSTEM LEAK TEST DEVICE



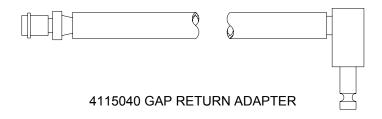


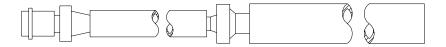


4115043 PDM TO MONITOR ADAPTER

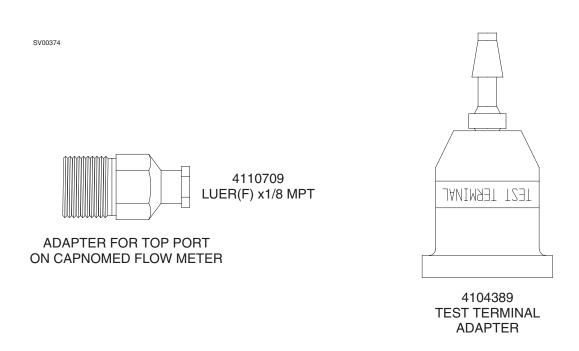


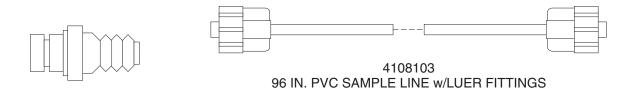
### 4115042 VOLUMETER/ FRESH GAS HOSE ADAPTER





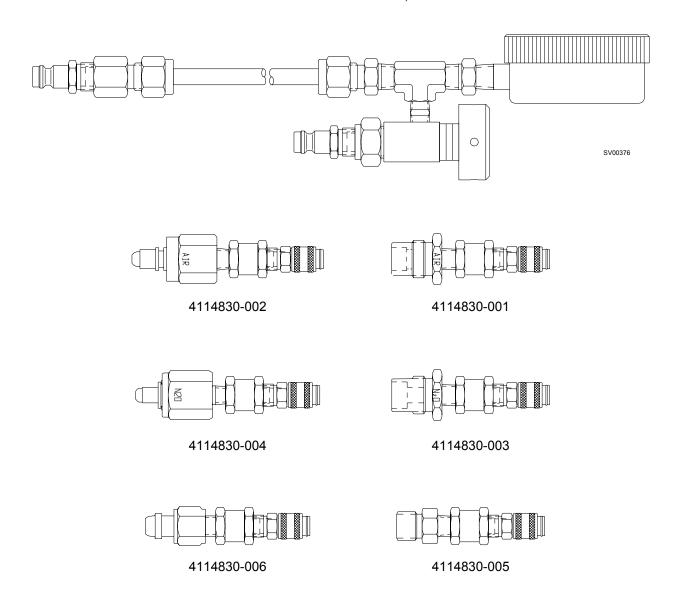
4115038 PDM TO PATIENT SUCTION ADAPTER

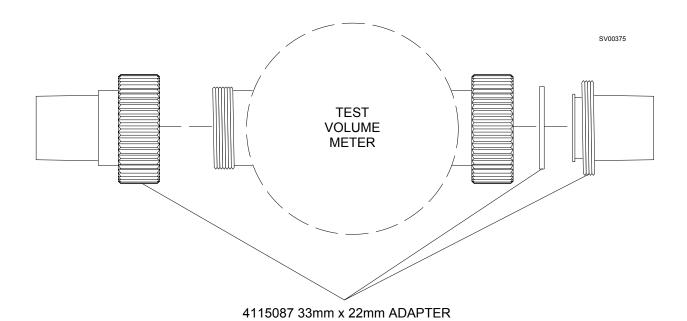




M31581 QDISC, MALE FRESH GAS

### 4114807 PRESSURE TEST ASSEMBLY, WITH ADAPTERS





6-9

PMC PROCEDURE (continued)

#### Periodic Manufacturer's Certification General Instructions

The purpose of these procedures is to provide detailed instructions for performing a Periodic Manufacturer's Certification (PMC) inspection on the Narkomed 6000 Series anesthesia machine.

A PMC consists of a complete Periodic Manufacturer's Service procedure and a certification level inspection based on Draeger Medical, Inc. Recommendations and equipment performance. Additional inspections are also performed to ensure proper product labeling.

Several additional documents have been created to assist the technician through the process. Following is a brief description of the purpose of each document.

Field Service Procedure:

Periodic Manufacturer's Certification Forms - Part Number SP00175.

This procedure illustrates the sample checklists with typical periodic maintenance items filled in, including vapor concentration verification tests, parts replaced, general comments and certification levels. Also included are sample PMC labels marked to show several levels of certifications. An excerpt from Draeger Medical, Inc.'s *Anesthesia System Risk Analysis and Risk Reduction* is included, and also a sample of an Executive Summary to be furnished to the hospital's Risk Manager or Chief of Anesthesia.

Field Service Procedure:

DMI Recommendation Guidelines Index Anesthesia Systems - Part Number S010250.

This Guideline was created to provide an assessment of each machine's certification. It contains various comprehensive overviews of possible equipment conditions and their associated certification levels.

The first list in the Recommendation Guidelines is a reference chart for machine certification based on equipment status. The second is an abbreviated summary of all DMI Recommendations and Failure Codes including the Condition Number, Equipment Condition, Recommended Corrections, Certification Code, and Tests Affected when applicable.

There is also a matrix classified as "Failure Codes" which identifies the correct manner in which to document equipment tests that fail, or were unable to be performed due to circumstances beyond the control of the service technician performing the inspection. (Ex: Air cylinder supply is unavailable to perform an Air High Pressure Leak test.) The Failure Codes section also indicates suggested resolution of the situation. Failure Code numbers begin at 34 and use the same certification levels strategy, and carry the same weight as NAD Recommendation equipment condition codes.

The final matrix is the most comprehensive index sorted by machine model and includes Equipment Condition, Certification Code, and DMI Recommendations. It also specifies any suggested upgrade path including ordering information that should be taken such as installing a Bellows with Pressure Limit Control 4109664-S01 Kit, after market modification kit to a machine not equipped with pressure limit control.

The letters A, B, C, D and the Roman Numerals I, II are used as codes in the individual matrix for each model of anesthesia machine. The letters A, B, C, and D are used in descending order to indicate the certification level of the equipment. They are as follows:

- A = Certified
- B = Certified with Recommendations
- C = Conditionally Certified
- D = No Certification

Roman Numerals I and II do not affect the certification level but rather are provided to give further instructions to the end user as follows:

- I = The system in its present configuration shall only be used with a CO<sub>2</sub> monitor incorporating an apnea warning. The operator of the system is advised to frequently scan the CO<sub>2</sub> readings and alarm thresholds.
- II = The present configuration of equipment requires that the unit operate at all times with an oxygen analyzer that includes a low oxygen warning. The operator of the system is advised to frequently scan the oxygen readings and alarm limits.

Following is an explanation of machine certification levels:

**Certified-** No recommendations apply to machine being inspected. (Only item number 33 - "No Recommendations" shall apply for this certification level.)

**Certified with Recommendations-** A numbered recommendation with a code of B applies to the machine being examined.

**Conditionally Certified-** A numbered recommendation with a code of BC, BCI or BCII applies to the machine being examined.

**No Certification-** A numbered recommendation with a code of D applies to the machine being examined.

When multiple recommendations apply, use the above list in descending order from bottom to top. For example, "No Certification would take precedence over "Conditionally Certified" and "Certified with Recommendations". "Conditionally Certified" would take precedence over "Certified with Recommendations".

For example:

A Narkomed 2B could have recommendation number 21 and failure code 61.1 apply.

- 21 No ventilator pressure limit control. Code is B.
- 61.1 Enflurane agent is unavailable to test. Code is BC.

Correct certification for this machine is BC, which means CONDITIONALLY CERTIFIED WITH RECOMMENDATIONS.

PMC PROCEDURE (continued)

A **Narkomed 4** could have recommendation numbers 14 and 21 apply.

14 -  $CO_2$ /Agent monitor exhaust port is not properly connected to the waste gas scavenger. Code B.

21 - No ventilator pressure limit control. Code B.

The correct certification for this machine is B, which means "CERTIFIED WITH RECOMMENDATIONS".

A Narkomed 2B, 2C or GS could have recommendation 30 apply.

30 - Anesthesia machine is equipped with inhalation anesthesia vaporizers without an agent analyzer in the breathing system. Code B.

The correct certification for this machine is B, which means "CERTIFIED WITH RECOMMENDATIONS".

A **Narkomed 6000** could have no NAD recommendations or failure codes apply. The correct certification level for this machine is Code A, "CERTIFIED".

Code D, which means "NO CERTIFICATION", also means the machine shall not receive a Periodic Manufacturer's Certification label. The machine shall also receive a "WARNING - This System is Not Certified" label, P/N 4114857. This label shall be placed at a prominent location on the right side of the machine after all other previous PM and "Vigilance Audit® Validation" labels have been removed.

#### PM Certification Procedure for Narkomed 6000 Series Anesthesia System

- 1. Use the PM Certification form P/N 4115093 for the Narkomed 6000 Series Anesthesia System. If the system is equipped with an Integrated Patient Monitor or Strip Chart Recorder, use the Integrated Monitor and Strip Chart form P/N 4116820.
- 2. Completely fill in the header information.
- 3. Perform the vapor concentration test on all Dräger vapor vaporizers every six months in accordance with SP00073 at a six month maximum interval. Perform the vaporizer concentration test on all D-Tec Desflurane vaporizers in accordance with SP00189 at a six month maximum interval. For every vaporizer tested, fill out a "VAPOR VAPORIZER CALIBRATION CHECK" label (part # S010016). Information on this label shall include your signature, type of agent, date tested, a No Agent To Test indication or the test results @ 1%, 2.5%, 4% for H, E, I, or S vaporizers, or @ 4%, 10%, 12%, 16% for Desflurane vaporizers, and a PASS or FAIL indication. This label shall be attached to the upper right side of the vaporizer. If vaporizer fails the concentration verification, internal leak, or exclusion system tests, check "NO" in the "RECOMMENDED FOR USE" section on the PM Certification form. Place a "CAUTION DO NOT USE" label (part # 4114327) on the vaporizer, and notify the customer. The TSR shall also seek permission from the customer to remove the failed vaporizer from the machine. All nonfunctional vaporizers must be removed from service for machine to receive certification.
- 4. Proceed with PM Certification in accordance with Section 6 and Section 6A if equipped with an Integrated Patient Monitor or Strip Chart Recorder. If any tests fail refer to the "Failure Codes" listing in DMI Recommendations Guidelines Index, P/N S010250, to determine the correct certification level starting point. Failure codes shall be documented on the "RECOMMENDATIONS / GENERAL COMMENTS" section of the PM Certification form and on the Executive Summary if applicable. If a test fails that has not been identified by the "Failure Codes" list, consult with Draeger Medical, Inc. to assess the proper certification level.
- 5. Based on the "EQUIPMENT CONDITION" inspect the machine for any "DMI RECOMMENDATIONS" that would apply. Use the Narkomed 6000 Series section of the "DMI RECOMMENDATION GUIDELINES INDEX", P/N S010250. Note all applicable DMI recommendations on the Executive Summary. NOTE: If using a carbon form, indicate the Equipment Condition number and see reverse side under "RECOMMENDATIONS / GENERAL COMMENTS" section of the form.

PMC PROCEDURE (continued)

# PM Certification Procedure for Narkomed 6000 Series Anesthesia System (continued)

- 6. Determine the correct certification level of the machine based on the combined lowest common denominator of "Equipment Conditions" and "Failure Codes". If the machine is at least conditionally certified, fill out the "PM CERTIFICATION" label. Check the box(es) on the validation label where appropriate. Write the month and year, (three months from date of PM Certification) next to "NEXT VISIT DUE:" If certification level is "D", machine shall not receive a "PM CERTIFICATION" label. Any machine not receiving a PM Certification label shall receive a "WARNING NOT CERTIFIED" label, P/N 4114857. This label shall be placed at a prominent location on the left side of the machine after all other previous PMS and Vigilance Audit Validation labels have been removed.
- 7. In the "CERTIFICATION LEVEL" section of the PM Certification form, record the last visit certification level, the current certification level and the next visit due month and year, (three months from date of PM Certification) in the spaces provided.
- 8. If applicable, remove the previous PM CERTIFICATION VALIDATION label and attach the new label (P/N S010006 w/phone #, or P/N S010007) in a prominent location on the rear of the anesthesia machine.
- 9. Check the appropriate boxes on the "PM CERTIFICATION NOTICE" label, (part # S010011). If the machine is not certified, the last box of this notice label shall be checked. Attach this notice to the flowmeter shield of the anesthesia machine.
- 10. Have the customer sign each PM Certification form or the Executive Summary, and review the equipment conditions and recommendations with the customer.
- 11. Return the top copy to Draeger Medical, Inc. Service Department, keep middle copy for service organization records, give bottom copy to customer.

#### 6.1 Service Menu

- $(\checkmark)$  6.1.1 Record the unit serial number located on the rear of the machine.
  - 6.1.2 If applicable, turn the System Power switch to ON, then press the Divan Standby key.
  - 6.1.3 Press the SETUP key to display the Setup Notebook
  - 6.1.4 Press the ABOUT tab to display the About page
  - 6.1.5 Press the following keys in this order:
    - (2)--Volume, Pressure, Oxygen
    - (3)--Gas Analysis
    - (1)--NM6000, or NM6400
    - (5)--Strip Chart Recorder
  - 6.1.6 Press OK to enter the Service Mode
  - 6.1.7 Press the NM6000, or NM6400 tab, the Service Config. key, and the NM6K tab.
  - 6.1.8 Press the PMC key.
  - 6.1.9 Enter your technical service ID and press OK.
  - 6.1.10 Refer to the machine's replacement components log and install any scheduled replacement parts required.
- (✓) 6.1.11 Record any scheduled parts replaced in the Service Log and on the report.

Scheduled parts replacement intervals are shown in the following tables.

# SCHEDULED REPLACEMENT PARTS ON NM6000

Interval	P/N	Description		Qty
	M29664	Roller Diaphragm (patient side)	4.9.1	1
6 Month Kit	8404065	Lip Seals (pneumatic interface)	4.9.4	5
P/N 4115074-001	4114887	Filter	N/A	1
	4115961	Semi-permeable tube	N/A	1
	4115864	O-ring (vapor mount)	N/A	4
	M29664	Roller Diaphragm (patient side)	4.9.1	1
1 Year Kit P/N 4115074-002	8404065	Lip Seals (pneumatic interface)	4.9.4	5
	4114887	Filter	N/A	1
	4115961	Semi-permeable tube	N/A	1
	8407979	Sealing Washer (breasy)	4.9.3	2
	8410181	Diaphragm (breasy)	4.9.3	2
	M30462	Diaphragm (breasy)	4.9.3	3
2 Year Kit	M27721	Lip Seal (piston interface to breasy)	4.9.4	1
P/N 4115074-003	8404065	Lip Seal (piston interface to Divan)	4.9.4	2
	4115864	O-ring (vapor mount)	N/A	4
	M29664	Roller Diaphragm (patient side)	4.9.1	1
	8404065	Lip Seals (pneumatic interface)	4.9.4	5
	4116144	Lithium Battery, 3V (WPU)	4.6.3	1
	4114887	Filter	N/A	1
	4115961	Semi-permeable tube	N/A	1

# PMC PROCEDURE (continued)

Interval	P/N	Description		Qty
3 Year Kit	1841688	Lithium Battery (TK-RAM, IRIA Po	CB) 4.1.1	1
	8301856	9V Battery (Divan motherboard)	4.9.2.6	1
	M29664	Roller Diaphragm (patient side)	4.9.1	1
P/N 4115074-004	8404065	Lip Seals (pneumatic interface)	4.9.4	5
	4115864	O-ring (vapor mount)	N/A	4
	4114887	Filter	N/A	1
	4115961	Semi-permeable tube	N/A	1
	M29320	Absorber	N/A	1
	M30455	Lip Seal	N/A	1
	M30456	Packing Ring	N/A	1
	1828142	DI-D Ram (TK-RAM, IRIA PCB)	4.1.1	1

# SCHEDULED REPLACEMENT PARTS ON NM6400

Interval	P/N	Description		Qty
6 Month Kit P/N 4118084	M29664	Roller Diaphragm (patient side) 4.	.9.1	1
	4115961	Semi-Permeable Tube	N/A	1
	8404065	Lip Seals (pneumatic interface) 4.	.9.4	5
	4115864	O-Ring (vapor mount)	N/A	5
4.74 163	M29664	Roller Diaphragm (patient side) 4.	.9.1	2
1 Year Kit P/N 4118085	8404065	Lip Seals (pneumatic interface) 4.	.9.4	5
	4115961	Semi-Permeable Tube	N/A	1
	6870567	Waterlock (12 Pack)	N/A	1
	8407979	Sealing Washer (breasy) 4.	.9.3	2
	8410181	Diaphragm (breasy 4.	.9.3	2
	M30462	Diaphragm (breasy) 4.	.9.3	3
	M27721	Lip Seal (piston to interface breasy) 4.	.9.4	1
	8404065	Lip Seals (piston interface to Divan) 4.	.9.4	2
2 Year Kit P/N 4118086	4115864	O-Ring (vapor mount)	N/A	4
	M29664	Roller Diaphragm (patient side) 4.	.9.1	1
	8404065	Lip Seals (pneumatic interface) 4.	.9.4	5
	4116144	Lithium Battery, 3V (WPU) 4.	.6.3	1
	4115961	Semi-Permeable Tube	N/A	1
	6870567	Waterlock (12 Pack)	N/A	1
	8601238	Tube Nafion GAP-2 (Internal) 4.2.	.9.4	1
	1841688	Lithium Battery(TK-RAM, IRIA PCB) 4.	.2.2	1
	8301856	9V Battery (Divan Motherboard) 4.9.	.2.6	1
	M29664	Roller Diaphragm (patient side) 4.	.9.1	1
	8404065	Lip Seals (pneumatic interface) 4.	.9.4	5
3 Year Kit P/N 4118087	4115864	O-Ring (vapor mount)	N/A	4
	M29320	Absorber	N/A	1
	M30455	Lip Seal	N/A	1
	M30456	Packing Ring	N/A	1
	4115961	Semi-Permeable Tube	N/A	1
	6870567	Waterlock (12 Pack)	N/A	1
	1828142	DI-D Ram (TK-RAM, IRIA PCB) 4.	.2.2	1

- 6.1.12 Press OK to exit the Replacement Parts Log.
- 6.1.13 Press the RESET LAST SERVICE DATE key.
- (✓) 6.1.14 Advance the PMC Due Date three months ahead and record this date.
  - 6.1.15 Press the Service Log key and press the Refresh key; identify any critical events.
  - 6.1.16 Press the Service Dump key
  - 6.1.17 Verify that GAP and VPO exception errors are all zeros. If fitted with IPMM (CV) or SCR, verify these pod exception errors are all zeros.
  - 6.1.18 Press the Service Monitors key to display the Service Monitors notebook
- ( $\checkmark$ ) Press the Oxygen tab and follow the instructions to perform an  $O_2$  zero calibration. After completing this calibration, expose the Oxygen Sensor capsule to room air.
- (✓) Press the Pressure tab and follow the instructions to perform a Zero and Span calibration.
- (✓) 6.1.21 Press the Screen tab and perform the touch screen calibration.

**NOTE:** An advanced touch screen calibration procedure is needed when calibration is not possible under the usual procedure. Refer to Section 5 for the complete procedures.

- 6.1.22 Press the Exit Service key.
- 6.1.23 Press the OK button at the bottom of the Service Mode window.

#### 6.2 Pressure Monitor

- 6.2.1 Adjust the test pressure to  $0 \text{ cm H}_2\text{O}$ .
- 6.2.2 If software version is  $\leq$  3.02, simultaneously set the ventilator to Man/Spontaneous Mode and start a stopwatch. If software version is  $\geq$  4.02, set the ventilator to Man/Spontaneous Mode then simultaneously press the pressure alarm bell and start a stopwatch.
- (✓) 6.2.3 Does the APNEA PRESSURE alarm appear on the display as a CAUTION within 27 to 33 seconds? (Y)
- ( $\checkmark$ ) 6.2.4 Slowly increase the test pressure. Does the APNEA PRESSURE alarm deactivate within 10 to 14 cm  $H_2O$ ? \_\_\_(Y)

- 6.2.5 First decrease the pressure, then increase the test pressure above the threshold line shown on the display, and begin timing with a stopwatch.
- (✓) 6.2.6 Does the CONTINUOUS PRES alarm appear as a warning within 13 to 17 seconds? \_\_\_(Y)
- (✓) Decrease the pressure slowly. Does the CONTINUOUS PRES alarm deactivate within 10 to 14 cm H<sub>2</sub>O? \_\_\_(Y)
- ( $\checkmark$ ) Slowly increase the test pressure. Does the VENT PRESS HI alarm activate as a warning within 45 to 55 cm H<sub>2</sub>O? \_\_\_(Y)
  - 6.2.9 Slowly create a sub-atmospheric test pressure.
- ( $\checkmark$ ) Does the SUB ATM PRES warning alarm activate within -7 to -13 cm  $H_2O?$  \_\_\_(Y)
  - 6.2.11 Remove test equipment.
  - 6.2.12 Turn the System Power switch to STANDBY.

### $(\checkmark)$ 6.3 Dusting and Lint Cleaning - One year service interval

**NOTE:** If the ambient air in the local environment contains a significant amount of dust and lint, the cleaning frequency must be increased to compensate for these conditions.

**WARNING:** Use only current-limiting vacuum cleaning devices (Ohmega Supreme or equivalent). Failure to observe this precaution may cause injury by electrical shock.

**CAUTION:** Use ESD precautions when handling any electronic assemblies. This machine contains static sensitive components. Use only ESD compatible vacuum cleaning devices (Ohmega Supreme or equivalent).

- 6.3.1 Turn the System Power switch to STANDBY.
- 6.3.2 Remove AC power from the machine. Wait at least 3 minutes for the system to shut down. After green LED on Vitalbus has extinguished, pull all circuit breakers to their 'out' position.

**CAUTION:** Pulling the DC Power circuit breaker with system power applied will crash the hard drive and may damage the WPU.

**WARNING:** Before servicing, ensure that AC power is removed from the machine and all circuit breakers are disengaged (pulled out). Failure to observe this precaution may cause injury by electric shock.

- 6.3.3 Close all cylinder valves and remove the cylinders from their yokes.
- 6.3.4 Remove the Vitalbus Hub mounting hardware (do not disassemble the hinge hardware). Remove the power cord strain relief and swing open the assembly.
- 6.3.5 Remove the lower and upper back panels. If fitted with a CRT, disconnect the fan's power cable.
- 6.3.6 If fitted with an IPMM, disconnect the Vitalbus cable and loosen the assembly's captive mounting screw, then slide the assembly out from its housing. Vacuum around the fan at the rear of the POD and the grille on the bottom of the assembly.
- 6.3.7 Disconnect the GAP's semi-permeable tube, Vitalbus cable, and exhaust hose. Loosen the assembly's captive mounting screw and slide the assembly out from its housing.
- 6.3.8 Remove the cover from the analyzer assembly. There are four screws on the bottom and one screw at the back.
- 6.3.9 Loosen the two upper screws securing the left side panel of the analyzer and swing open the panel.
- 6.3.10 Vacuum debris from the assembly and pay particular attention to the fan at the rear of the POD and the grille on the bottom of the assembly.
- 6.3.11 Close the left hinged side of the analyzer and tighten the retaining screws.
- 6.3.12 Reinstall the cover on the analyzer.
- 6.3.13 Vacuum inside POD housings and pay particular attention to the bottom cockpit cover grille.
- 6.3.14 If fitted with an IPMM, slide the assembly into its upper housing. Tighten its retaining screw and reconnect the Vitalbus cable.
- 6.3.15 Slide the GAP into its lower housing and tighten its retaining screw. Reconnect the semi-permeable tube, Vitalbus cable, and exhaust hose.
- 6.3.16 Vacuum inside the CRT/flat panel housing. If fitted with a CRT, vacuum around this assembly and the fan mounted to the top back panel.
- 6.3.17 Vacuum the WPU's power supply fan ventilation grille located at the right side panel of the assembly.

- 6.3.18 Vacuum the Vitalbus fan and ventilation grille.
- 6.3.19 Vacuum the power supply ventilation grills located on the left and right sides of the assembly.
- 6.3.20 If fitted with a CRT, reconnect the fan's power cable. Install the lower and upper back panels.
- 6.3.21 Close the Vitalbus Hub door. Reattach the power cord strain relief and secure the assembly.
- 6.3.22 Reattach the cylinders to their yokes.
- 6.3.23 Reset all circuit breakers to their 'in' position. Restore AC power to the machine.

# 6.4 Open Reservoir Scavenger Cleaning - Six month service interval, if applicable

**NOTE:** If the ambient air in the local environment contains a significant amount of dust and lint, the cleaning frequency must be increased to compensate for these conditions.

- 6.4.1 Remove the scavenger hose and drain any accumulated moisture. Inspect the hose for deterioration and replace it if needed.
- 6.4.2 Disconnect the hospital vacuum source from the scavenger.
- 6.4.3 Remove the four screws securing the reservoir tube to the main block. Examine the two sealing O-rings and replace as necessary.
- 6.4.4 Remove the four screws securing the access panel at the bottom of the scavenger canister.
- 6.4.5 Remove and inspect the silencer; replace if needed.
- 6.4.6 Clean the reservoir tube with compressed air if necessary.
- 6.4.7 Remove the flowmeter tube from its housing by turning it counterclockwise. Examine the sealing O-ring and replace as necessary.
- 6.4.8 Inspect the flowmeter tube and clean it with compressed air if needed.
- 6.4.9 Peel back the tape covering the lower flowmeter housing screw, and remove the screws securing the flowmeter housing. Examine the sealing O-ring and replace as necessary.
- 6.4.10 Fully open the flow control valve and remove the assembly by unthreading the retaining hex nut.

- 6.4.11 Remove the two screws securing the adapter plate to the main block. Examine the sealing O-rings and replace as necessary.
- 6.4.12 Probe all gas passages of the main block to ensure there are no occlusions. Clean with compressed air if necessary.
- 6.4.13 Reassemble the scavenger, attach the scavenger hose and reactivate the vacuum source.

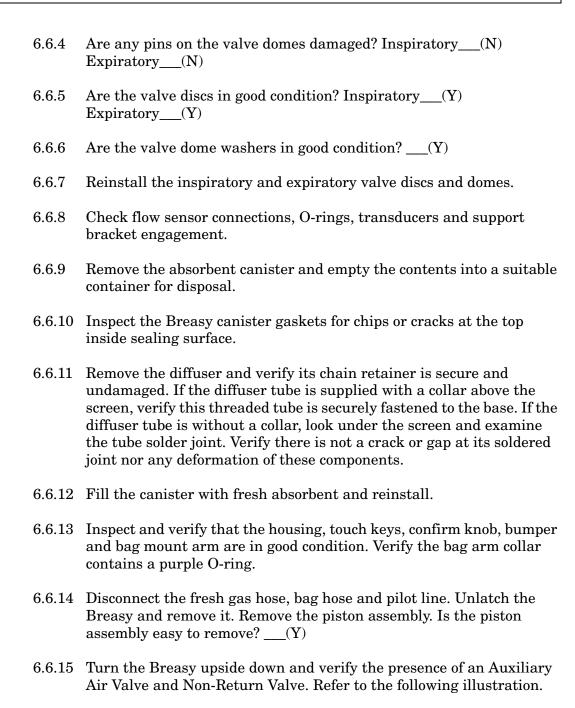
# $(\checkmark)$ 6.5 A/C Scavenger Cleaning - Six month service interval, if applicable

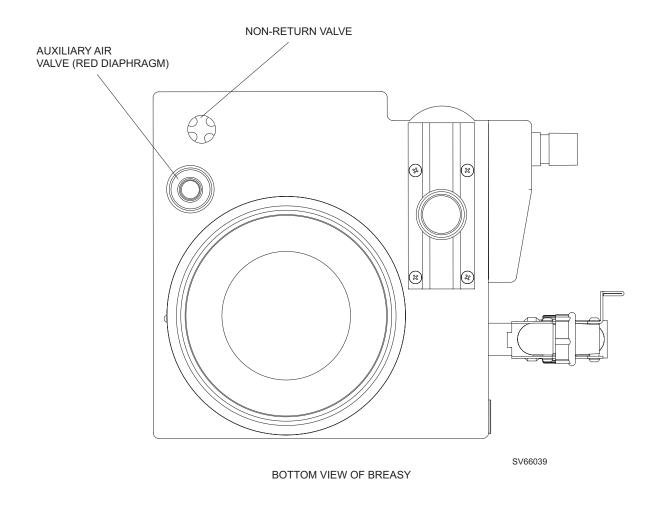
**NOTE:** If the ambient air in the local environment contains a significant amount of dust and lint, the cleaning frequency must be increased to compensate for these conditions.

- 6.5.1 Remove the scavenger hose and drain any accumulated moisture. Inspect the hose for deterioration and replace it if needed.
- 6.5.2 Remove the safety relief valve housing by unscrewing it in a counterclockwise direction.
- 6.5.3 Inspect the O-ring and replace it if needed.
- 6.5.4 Remove the safety relief valve from its housing by twisting it out in a counter-clockwise direction. The tips of locking needle-nose pliers can be used to turn the valve. Be careful not to damage the valve's fragile disk.
- 6.5.5 Remove any accumulated lint or dust from the valve with a soft brush. The valve may be further cleaned with a low flow of air or oxygen.
- 6.5.6 Reinstall the valve into the housing, making sure that it is seated all the way into the housing and that the plastic washer is properly seated on its upper surface.
- 6.5.7 Reinstall the valve housing onto the scavenger body, making sure that the O-ring is properly seated.

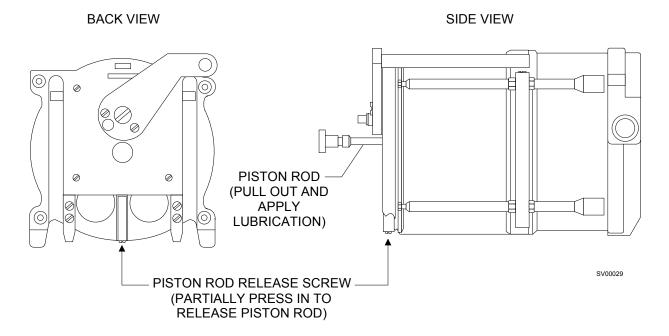
# $(\checkmark)$ 6.6 Divan Inspections

- 6.6.1 Remove the oxygen sensor or the plug from the inspiratory valve dome adapter. Examine the O-rings on each assembly and replace as necessary.
- 6.6.2 Remove the inspiratory and expiratory valve domes and discs.

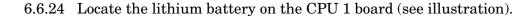


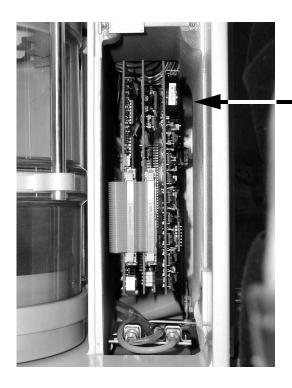


- 6.6.16 Inspect and verify that the compact breathing system and piston assemblies are in good condition.
- 6.6.17 Partially press the piston rod release screw, and pull the piston rod out (see illustration).



- 6.6.18 Verify the piston rod does not show signs of excessive wear. Wipe off any old lubricant and wear debris.
- 6.6.19 Apply a thin film of Molykote 55 lubricant (P/N 4115127) to the rod.
- 6.6.20 Verify the locking mechanism operates correctly. Lubricate the drive block that pulls the breathing system to the pneumatic interface with Molykote 55M.
- 6.6.21 Verify all support points are tight. Locking plate M29663 or rod locking mechanism must not be bent.
- 6.6.22 Examine the lip seals on the piston, piston cylinder housing, and Breasy interface and verify that they are in good condition and not deformed.
- 6.6.23 Remove the two screws securing the PCB cover plate. Lift out the plate and board retainer.





If the battery does not have a "Replace By..." label, the required replacement interval must be established. Refer to paragraph 4.9.2.1, Lithium Battery Replacement. If the battery has a 'Replace By" label and the date on the label is less than three months in the future, replace the battery. Refer to paragraph 4.9.2.1.

(✓) 6.6.25 Record the next CPU-1 battery replacement date.

# (√) 6.7 High Pressure Leak

**NOTE:** Minimum cylinder pressures for the High Pressure Leak tests are:

 $N_2O$ : 600 psi  $O_2$ , Air: 1000 psi

- 6.7.1 Verify the Auxiliary Oxygen flow control valve is closed.
- 6.7.2 Disconnect all pipeline supply hoses at the wall outlets.
- 6.7.3 Open, then close and remove each cylinder. If applicable, remove the yoke plug from each additional yoke assembly.
- 6.7.4 Note the reading on each cylinder pressure gauge and start a stopwatch.

		6.7.5	Are the two (2) yoke index pins installed securely in each yoke?(Y)		
		6.7.6	After two (2) minutes, is the pressure loss equal or less than 50 psi? $\underline{\hspace{1cm}}(Y)$		
		6.7.7	Verify the presence of only one sealing washer; reattach and secure the cylinders to each yoke assembly, then open each cylinder valve.		
	6.8	Fresh G	Gas Leak / Exclusion / Solenoid / O <sub>2</sub> Flush		
		6.8.1	Connect a digital pressure manometer and special Fresh Gas Leak Test Device (P/N 4115041) to the fresh gas hose.		
		6.8.2	Apply 50 cm $\rm H_2O$ of pressure to the fresh gas system and start a stopwatch.		
<b>(√)</b>		6.8.3	After 30 seconds, is the fresh gas pressure equal or greater than 40 cm $\rm H_2O? \ \_\_(Y)$		
		6.8.4	Move the exclusion bar to the right and verify it does not bind. If applicable, turn on the left mounted vaporizer to the first graduated marking. Reapply 50 cm $\rm H_2O$ of pressure to the test circuit and start a stopwatch. Verify it is not possible to turn either the upper or right vaporizers.		
<b>(√)</b>		6.8.5	After 30 seconds, is the left vaporizer test pressure equal or greater than 40 cm $\rm H_2O$ ?(Y)		
		6.8.6	Turn off the vaporizer.		
		6.8.7	Open the valve on the test bulb.		
		6.8.8	Move the exclusion bar to the right and verify it does not bind. If applicable, turn on the right mounted vaporizer to the first graduated marking. Close the valve on the test bulb, then apply 50 cm $\rm H_2O$ of pressure to the test circuit and start a stopwatch. Verify it is not possible to turn either the upper or left vaporizers.		
<b>(√)</b>		6.8.9	After 30 seconds, is the right vaporizer test pressure equal or greater than 40 cm $H_2O$ ?Y		
		6.8.10	Turn off the left vaporizer.		
		6.8.11	Open the valve on the test bulb.		

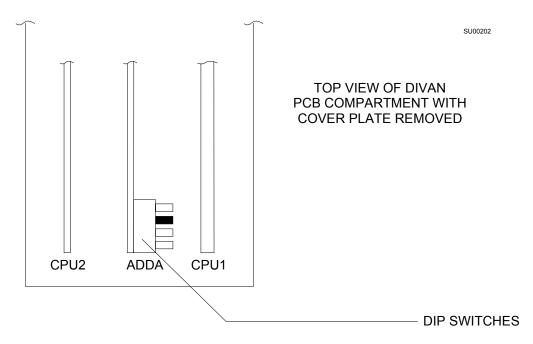
	6.8.12	bind, th marking pressur	cable, move the exclusion bar upwards and verify it does not en turn on the upper mounted vaporizer to the first graduated g. Close the valve on the test bulb then apply 50 cm $\rm H_2O$ of e to the test circuit and start a stopwatch. Verify it is not e to turn either the left or right vaporizers.	
<b>(√)</b>	6.8.13		) seconds, is the upper vaporizer test pressure equal or greater cm $H_2O?$ ( $Y$ )	
	6.8.14	Turn of	f the vaporizer.	
	6.8.15	Open th	ne valve on the test bulb.	
<b>(√)</b>	6.8.16	Did all	the vaporizer exclusion verifications test positive?(Y)	
	6.8.17	Turn th	e System Power switch to ON.	
	6.8.18	_	he Divan start-up self test but Do Not respond to the FRESH FF message.	
	6.8.19		he minimum $\rm O_2$ flow is disabled, close the valve on the test d apply 50 cm $\rm H_2O$ of pressure to the system.	
<b>(√)</b>	6.8.20	After 30 H <sub>2</sub> O?	seconds, is the Solenoid test pressure equal or less than 55 cm	
	6.8.21		the Volumeter/Fresh Gas Adapter (P/N 4115042) to the top the test volumeter.	
	6.8.22		the Fresh Gas Leak Test Device from the fresh gas hose and the test volumeter.	
	6.8.23	Press th	ne $O_2$ Flush button for 6 seconds and multiply the indicated y ten.	
<b>(√)</b>	6.8.24	Is the o	xygen flush flow rate within 45 to 65 L/min?(Y)	
	6.8.25	Remove	the test volumeter and adapter from the fresh gas hose.	
6.9	Divan	Service Menu		
<b>(√)</b>	6.9.1	Error Lo	g	
		6.9.1.1	Turn the System Power switch to STANDBY and wait until the display goes blank.	

- 6.9.1.2 Start the Divan in the Service Mode by pressing the left pad of the Standby button and the pad above it while turning the System Power switch to ON.
- 6.9.1.3 Turn the knob to display LOGBOOK and press the knob.
- 6.9.1.4 Review the last ten logbook entries and take corrective action as necessary.

**NOTE:** Address area of logbook \$0000 to \$004F most recent error can be found at address [0000].[0000] xxx yyH (xxx error in decimal form, yy error in hexadecimal form).

**CAUTION:** Use ESD precautions via use of Field Static Kit (P/N S000095) when handling the PCB assemblies. Static discharge can damage components on these assemblies.

- 6.9.1.5 Set the 3rd DIP switch on the ADDA PCB (see illustration) to the down position.
- 6.9.1.6 Press the Pmax key to reset the display to [0000] 000 00 H.
- 6.9.1.7 Return the 3rd DIP switch to its original (up) position.
- 6.9.1.8 Replace the PCB retainer and cover plate, and secure it with the screws that were previously removed.
- 6.9.1.9 Press the knob to exit the function.



<b>(✓)</b>	6.9.2	Confirm	n Mode Verification
		6.9.2.1	Turn the knob to display Confirm Mode.
		6.9.2.2	Press the knob to display Confirm R-knob, then press the knob.
		6.9.2.3	Exit the function by turning the knob.
<b>(√)</b>	6.9.3	Power-	up Default Settings
		6.9.3.1	Turn the rotary knob to display "Select Parameter", then press the knob to confirm selection. The display will then indicate Default Settings.
		6.9.3.2	Referring to the following chart, touch each key to display the current default value. If a parameter requires adjustment, rotate the knob to set the correct value:
			Parameter PmaxSetting 30 @ Software Version 7.40I:E1.0: 2.0
		6.9.3.3	Press the rotary knob twice to exit the function.
<b>(√)</b>	6.9.4	Breathi	ng System Heater Check:
		6.9.4.1	Verify the heater plate surface is cool.
			<b>NG:</b> The temperature of the heater plate may be as high as mately $150^{\circ}$ F ( $65^{\circ}$ C).
		6.9.4.2	Press down on the heater plate surface with your hand.
		6.9.4.3	Verify that the heater plate surface temperature increases.
		6.9.4.4	Remove the pressure from the heater plate contact surface; verify that the heater plate returns to its original position and begins to cool.
<b>(√)</b>	6.9.5	Pressure	e Sensor Zero Calibration
		6.9.5.1	Turn the knob to display CONFIG VALVES, and press the knob.
		6.9.5.2	Press the PEEP button on the control panel to vent control pressure. Display should indicate xxx000001.
		6.9.5.3	Press the knob.

- 6.9.5.4 Turn the knob to display A/D CONVERTER, and press the
- 6.9.5.5 Verify that the CHANNEL 0 (PE1) display shows a decimal value (left side of numeric display) within 506 and 717.
- 6.9.5.6 Turn the knob to select Channel 1 (PE2).
- 6.9.5.7 Verify that the CHANNEL 1 display shows a decimal value (left side of numeric display) within 506 and 717.
- 6.9.5.8 Press the knob to exit the function.
- (✓) 6.9.6 Pressure Sensor Linearity Test
  - 6.9.6.1 Turn the knob to select 'CALIB SENSORS?' and press the knob to perform the calibration. Display should first indicate SENSOR CALIB! and then return to CALIB SENSORS?.

**CAUTION:** The Piston assembly must be removed and the Breasy unlatched from the pneumatic interface prior to performing this calibration.

- 6.9.6.2 Turn the knob to select CONFIG VALVES and press the knob. Display should indicate xxx000000.
- 6.9.6.3 Press the knob to exit the function.
- 6.9.6.4 Turn the knob to select DISP. PRESS. VAL. and press the knob. The display shows xxxx yyyy zzzz where:

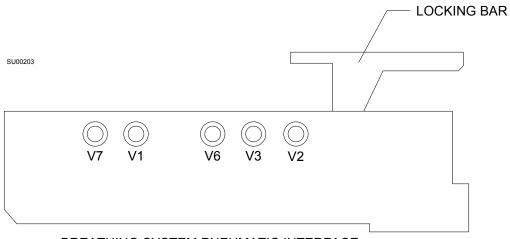
xxxx indicates PE1 pressure (Airway) in 1/10 cm  $\rm H_2O$  yyyy indicates PE2 pressure (Piston) in 1/10 cm  $\rm H_2O$  zzzz indicates PE3 pressure (Control) in 1/10 cm  $\rm H_2O$ 

**NOTE:** Airway pressure display should indicate  $\pm$  20 counts (0  $\pm$ 2 cm H<sub>2</sub>O).

- 6.9.6.5 Install the piston and compact breathing system, and restore the breathing system connections including the test breathing circuit. Compact breathing system must be parallel to the pneumatic interface and must be horizontal.
- 6.9.6.6 Set the APL to  $30 \text{ cm H}_2\text{O}$ .
- 6.9.6.7 Remove the test breathing bag hose from the telescoping pole and connect it to the Y-piece.
- 6.9.6.8 Connect a test pressure meter and GAP return adapter (P/N 4115040) to the gas sample return port.

- 6.9.6.9 Open the air or oxygen flow control valve so that the pressure can build up and APL enters its working range. Readjust APL valve if necessary to maintain  $30 \text{ cm H}_2\text{O}$  on the test pressure meter.
- 6.9.6.10 Verify that PE1 and PE2 displays do not differ by more than +/-30 count (3 cm  $H_2O$ ).
- 6.9.6.11 Press the knob to exit the function.
- 6.9.6.12 Close the flow control valve.
- (✓) 6.9.7 Vacuum Relief Valve if applicable
  - 6.9.7.1 Turn the knob to display "conf. valves" and press the knob.
  - 6.9.7.2 Press the Pmax and Vt keys. Display should indicate "xxx110000".
  - 6.9.7.3 Reconnect the bag hose to the bag arm.
  - 6.9.7.4 Connect a test terminal (P/N 4104389) to the test patient circuit Y-piece. Connect a suction squeeze bulb (such as a Riken aspirator) to the test terminal. Alternately a vacuum source providing at least 50 mm Hg may be used.
  - 6.9.7.5 Activate the vacuum source or squeeze the suction bulb several times to evacuate the gas volume in the Piston and develop a working negative pressure.
  - 6.9.7.6 Verify a maximum pressure of -25 to -45 cm  $\rm H_2O$  is displayed on the test pressure meter.
  - 6.9.7.7 Remove the test gauge and GAP return adapter.
- (✓) 6.9.8 PE3 Sensor and Control Pressure Check
  - 6.9.8.1 Turn the knob to display CONFIG VALVES, then press the knob. Display should indicate xxx 000000.
  - 6.9.8.2 Press, then turn the knob to select DISP. PRESS. VAL. and press the knob. The display shows xxx yyy zzz where:
    - xxxx indicates PE1 pressure (Airway) in  $1/10 \text{ cm H}_2\text{O}$  yyyy indicates PE2 pressure (Piston) in  $1/10 \text{ cm H}_2\text{O}$  zzzz indicates PE3 pressure (Control) in  $1/10 \text{ cm H}_2\text{O}$
  - 6.9.8.3 Unlock the compact breathing system from the pneumatic interface.

- 6.9.8.4 Occlude the V2 and V7 ports.
- 6.9.8.5 Divan display should indicate within 830 to 910 counts (83 to 91 cm  $\rm H_2O$ ) for PE3.
- 6.9.8.6 Lock the compact breathing system.
- 6.9.8.7 Press the knob to exit the function.



BREATHING SYSTEM PNEUMATIC INTERFACE (VIEW FROM LEFT SIDE WITH BREATHING SYSTEM REMOVED)

- (✓) 6.9.9 Secondary Control Pressure
  - 6.9.9.1 Turn the knob to display CONFIG VALVES, then press the knob.
  - 6.9.9.2 Press the RATE button. Display should indicate xxx0010000.
  - 6.9.9.3 Press the knob to exit the function.
  - 6.9.9.4 Turn the knob to select DISP. PRESS. VAL., and press the knob. The display shows xxx yyy zzz where:
    - xxxx indicates PE1 pressure (Airway) in 1/10 cm  $\rm H_2O$  yyyy indicates PE2 pressure (Piston) in 1/10 cm  $\rm H_2O$  zzzz indicates PE3 pressure (Control) in 1/10 cm  $\rm H_2O$
  - 6.9.9.5 Display should indicate within 770 to 970 counts (77 to 97 cm  $H_2O$ ) for PE3.

**NOTE:** If test fails, check breathing system diaphragm integrity at location Y2. Also verify 1.5 bar ventilator supply pressure, 2 L/min. ventilator flow, and if either parameter is adjusted, the 87 mbar control pressure also requires calibration. Refer to Sections 4.9.3, 5.12, 5.13, and 5.14.

- 6.9.9.6 Press the knob to exit the function.
- 6.9.10 Expiration Valve Leak
  - 6.9.10.1 Turn the knob to display Conf. Valves, then press the knob. Display should indicate xxx000000.
  - 6.9.10.2 Turn the knob to select DISP. PRESS. VAL., and press the knob. The display shows xxx yyy zzz where:
    - xxxx indicates PE1 pressure (Airway) in 1/10 cm  $\rm H_2O$  yyyy indicates PE2 pressure (Piston) in 1/10 cm  $\rm H_2O$  zzzz indicates PE3 pressure (Control) in 1/10 cm  $\rm H_2O$
  - 6.9.10.3 Interconnect a hose between the Divan bag port and the inspiratory valve.
  - 6.9.10.4 Connect a test terminal (P/N 4104389) to the expiratory port on the flow sensor.
  - 6.9.10.5 Connect a flowmeter (P/N S000081) to the test terminal.
  - 6.9.10.6 Turn up the oxygen flow until PE1 indicates approximately  $300 \text{ counts } (30 \text{ cm H}_2\text{O}).$
  - 6.9.10.7 Is the flow indicated on the test flowmeter equal to or less than 60 ml/min.?  $\underline{\hspace{1cm}}(Y)$ .
  - 6.9.10.8 Close the oxygen flow control valve.
- (✓) 6.9.11 Inspiratory Valve Leak
  - 6.9.11.1 Interconnect a hose between the Divan bag port and the expiratory port on the flow sensor.
  - 6.9.11.2 Connect a test terminal to the inspiratory valve and attach a hose between the test terminal and the Auxiliary Oxygen flow meter.
  - 6.9.11.3 Connect a flowmeter (P/N S000081) to the Q-disc male fresh gas test (P/N M31581) connector (ref. test equipment illustrations at front of PMC procedure), and attach a fresh gas male test connector to the fresh gas port of the Breasy.
  - 6.9.11.4 Adjust the Auxiliary Oxygen flow control valve to maintain a pressure of approximately 30 cm  $\rm H_2O$  on PE1.
  - 6.9.11.5 Is the flow indicated on the test flowmeter equal or less than 60 ml/min.?  $\underline{\hspace{1cm}}(Y)$

- 6.9.11.6 Remove the test equipment; reconnect the fresh gas and bag hoses, and test patient circuit.
- 6.9.11.7 Close the Auxiliary  $O_2$  flow control valve.
- (✓) 6.9.12 Ventilator Override
  - 6.9.12.1 Lift the guard on the ventilator override switch, press and hold the button until the LED indicator lights.
  - 6.9.12.2 Connect a test lung to the Y-piece.
  - 6.9.12.3 Verify that manual ventilation can be performed with the breathing bag.
  - 6.9.12.4 Turn the System Power switch to STANDBY.
  - 6.9.13 Power-Up Divan Check
    - 6.9.13.1 Turn the System Power switch to ON.
    - 6.9.13.2 Follow the operator prompts on the control panel to complete the Divan self test.
- ( $\checkmark$ ) 6.9.13.3 Is the leak rate equal or less than 100 ml/min.? \_\_\_(Y)
  - 6.9.13.4 Verify that all System Power-up Self Diagnostic tests are successfully completed.
- $(\checkmark)$  6.10 Suction Switch Six month service interval
  - 6.10.1 Remove the patient suction assembly.
  - 6.10.2 Set the suction switch to the closed (down) position.
  - 6.10.3 Activate the hospital vacuum pipeline supply.
  - 6.10.4 Connect a digital pressure meter and suction adapter w/squeeze bulb (P/N 4115039) to the suction fitting on the left side of the NM6000.
  - 6.10.5 Pressurize the connection to  $50 \text{ cm H}_2\text{O}$ .
  - 6.10.6 After 10 seconds, is the test pressure equal or greater than 30 cm  $H_2O?$  \_\_\_(Y)
  - 6.10.7 Remove the squeeze bulb and replace it with a test terminal (P/N 4104389), 33mm x 22mm adapter (P/N 4115087) and volumeter.
  - 6.10.8 Set the suction switch to the open (up) position.

- 6.10.9 Is the suction pipeline flow rate equal or greater than 30 L/min.? (Y)
- 6.10.10 Remove all test equipment and reconnect the patient suction assembly.

#### $(\checkmark)$ 6.11 Suction Regulator - Six month service interval, if applicable

- 6.11.1 Set the vacuum regulator's on/off valve to the OFF (vertical) position.
- 6.11.2 Using a PDM/suction adapter (P/N 4115038), connect a digital pressure meter to the collecting inlet stem of the suction bottle.
- 6.11.3 Set the digital pressure meter to the mmHg scale.
- 6.11.4 Turn the vacuum regulator control knob to its fully counter-clockwise open position.
- 6.11.5 Verify the vacuum indicated on the digital pressure meter does not rise.
- 6.11.6 Turn the vacuum regulator control knob fully clockwise and verify that the knob has a functional mechanical stop.
- 6.11.7 Set the vacuum regulator on/off valve to the ON (horizontal) position.
- 6.11.8 Set the regulator to indicate 250 mmHg.
- 6.11.9 Is the vacuum indicated on the digital pressure meter within 200 to 300 mm Hg? (Y)
- 6.11.10 Remove the test equipment and return all controls to their original positions.

#### 6.12 Oxygen Analyzer

6.12.1 Touch the O<sub>2</sub> CAL softkey and select YES in the confirm window.

**NOTE:** Make sure the sensor is exposed to only 21%  $O_2$  (room air).

- (✓) 6.12.2 After calibration is completed, is the displayed oxygen concentration 21%? \_\_\_(Y)
  - 6.12.3 The Warning message % OXYGEN LOW shall appear on the central alarm display, and a continuous audible alarm shall sound.

	6.12.4	SPONT valve to	e Oxygen sensor into the Inspiratory valve dome. Select MAN/ on the Divan. Disable the Paw and Vol alarms. Set the APL ggle switch to MAN. Remove the test breathing bag and it with a squeeze bulb (P/N S010159). Remove the Y-piece from plug.
	6.12.5	Press th	he ${ m O_2}$ Flush.
	6.12.6	After 10 (Y)	seconds, is the oxygen concentration within 90 to 100%?
	6.12.7	Release	the $O_2$ Flush. Does the flow cease immediately?(Y)
	6.12.8	Set the	oxygen flow to 10 L/min.
<b>√</b> )	6.12.9	After on(Y)	the minute, is the oxygen concentration within 97 to 100%?
	6.13 Flowm	eters/Ga	s Concentration/EFG Measurement
<b>√</b> )	6.13.1	Oxygen	Flowmeter
		6.13.1.1	Is it possible to adjust the flow of oxygen over the full range of the flowmeters? $\underline{\hspace{1cm}}(Y)$
		6.13.1.2	Is the correct flow control knob and label attached to the oxygen flow control valve? $\underline{\hspace{1cm}}(Y)$
<b>√</b> )	6.13.2	Air Flow	meter
		6.13.2.1	If not configured with an Air cylinder valve, attach the Air pipeline hose.
		6.13.2.2	Set the oxygen flow to 4 L/min.
		6.13.2.3	Is it possible to adjust the flow of Air over the full range of the flowmeter? $\underline{\hspace{1cm}}(Y)$
		6.13.2.4	Set the Air flow to 2 L/min.
		6.13.2.5	After the value stabilizes, is the oxygen concentration within 71 to 77%?(Y)
		6.13.2.6	If configured with Electronic Fresh Gas Measurement, select the 'To Secondary Keys' button. Select the 'Utilities Notebook'. Select the 'Fresh Gas Info' tab. Is the Fresh Gas Info displayed for Oxygen within 3.5 and 4.5 and the Air

per minute? \_\_\_(Y)

within 1.7 and 2.3 and the total flow within 5.2 to 6.8 liters

		6.13.2.7	Close the Air flow control valve.
		6.13.2.8	Is the correct flow control knob and label attached to the Air flow control valve? $\underline{\hspace{1cm}}(Y)$
<b>(√)</b>	6.13.3	Nitrous (	Oxide Flowmeter
		6.13.3.1	If not configured for a nitrous oxide cylinder valve, attach the Nitrous Oxide pipeline hose.
		6.13.3.2	Set the nitrous oxide flow to 2 L/min.
		6.13.3.3	After the value stabilizes, is the oxygen concentration 64 to $70\%$ ?(Y)
		6.13.3.4	If configured with Electronic Fresh Gas Measurement, is the Fresh Gas Info displayed for Nitrous Oxide within 1.7 and 2.3 and the total flow within 5.2 to 6.8 liters per minute?(Y)
		6.13.3.5	Is it possible to adjust the flow of nitrous oxide over the full range of the flowmeters? $\underline{\hspace{1cm}}(Y)$
		6.13.3.6	Is the correct flow control knob and label attached to the Nitrous Oxide flow control valve? $\underline{\hspace{1cm}}(Y)$
	6.13.4	Oxygen	Ratio Control
		6.13.4.1	Open the nitrous oxide flow control to its stop position.
<b>(</b> ✓)		6.13.4.2	After the value stabilizes, is the oxygen concentration within 21 to 29%?(Y)
		6.13.4.3	Set the oxygen flow to 2 L/min.
<b>(✓)</b>		6.13.4.4	After the value stabilizes, is the oxygen concentration within 21 to 29%?(Y)
		6.13.4.5	Set the oxygen flow to 1 L/min.
<b>(√)</b>		6.13.4.6	After the value stabilizes, is the oxygen concentration within 21 to 29%?(Y)
		6.13.4.7	Reduce the $\rm O_2$ flow to 500 ml/min. Verify that the $\rm N_2O$ flow is greater than or equal to 600 ml/min.
		6.13.4.8	Close the oxygen flow control valve.

- 6.13.4.9 If the machine can be configured for Air Only mode, engage this feature and verify the minimum  $O_2$  and  $N_2O$  bypass flows stop. Then press the  $O_2/N_2O/AIR$  key to disengage this feature.
- 6.13.4.10 Close the  $N_2O$  flow control valve.
- 6.13.4.11 Press the Divan Stand By key and press the confirm knob.
- (✓) 6.13.5 Auxiliary Oxygen Flowmeter Test
  - 6.13.5.1 Connect a test pressure monitor to the outlet using a PDM adapter (P/N 4115033).
  - 6.13.5.2 Bleed any pressure from the test device.
  - 6.13.5.3 Is there an increase in pressure? \_\_\_(N)
  - 6.13.5.4 Increase the pressure to  $50 \text{ cm H}_2\text{O}$ .
  - 6.13.5.5 After 30 seconds, is the pressure within 30 to 50 cm  $\rm H_2O$ ? (Y)
  - 6.13.5.6 Remove the test gauge and adapter.
  - 6.13.5.7 Is it possible to adjust the flow over the full range of the flowmeter? \_\_\_(Y)
  - 6.13.5.8 Set the flow rate to 5 L/min.
  - 6.13.5.9 Hold the Oxygen sensor at the flowmeter outlet.
  - 6.13.5.10 After the value stabilizes, is the oxygen concentration equal or greater than 80%? \_\_\_(Y)
  - 6.13.5.11 Replace the Oxygen sensor into the Inspiratory valve dome.
  - 6.13.5.12 Close the Auxiliary Oxygen flow control valve.

#### 6.14 High Pressure Regulator - Six month service interval

( $\checkmark$ ) 6.14.1 N<sub>2</sub>O Regulator - if applicable

**NOTE:** Minimum cylinder pressure for N<sub>2</sub>O regulator test is 600 psi.

 $\begin{array}{cccc} 6.14.1.1 & Configure the test gauge (P/N~4114807)~using a~N_2O~nut/stem\\ & DISS~connector~(P/N~4114830-004)~on~the~hose,~and~N_2O\\ & DISS~body~connector~(P/N~4114830-003)~on~the~valve~body\\ & side. \end{array}$ 

- 6.14.1.2 Connect the test fixture hose to the machine's nitrous oxide pipeline inlet.
- 6.14.1.3 Connect the nitrous oxide pipeline supply hose to the test fixture.
- 6.14.1.4 Set the oxygen and nitrous oxide flows to 4 L/min.
- 6.14.1.5 Depress the push button on the test device.
- 6.14.1.6 Release the push button. After the pressure decay stabilizes, is the regulator output pressure within 40 to 49 psi? \_\_\_(Y)

**NOTE:** If a pressure decrease does not occur, either the hospital's supply pressure is too low or the regulator pressure is set too high.

(√) 6.14.2 Air Regulator - if applicable

**NOTE:** Minimum cylinder pressure for Air regulator test is 1000 psi.

- 6.14.2.1 Configure the test gauge (P/N 4114807) using an Air nut/stem DISS connector (P/N 4114830-002) on the hose and a DISS body connector (P/N 4114830-001) on the valve body side.
- 6.14.2.2 Connect the test fixture hose to the machine's air pipeline inlet.
- 6.14.2.3 Connect the air pipeline supply hose to the test fixture.
- 6.14.2.4 Set the air flow to 4 L/min.
- 6.14.2.5 Depress the push button on the test device.
- 6.14.2.6 Release the push button. After the pressure decay stabilizes, is the regulator output within the tolerance given in the following table? (Y)

Cylinder Pressure psi	USA Compensated Regulator output tolerances	ISO Compensated Regulator output tolerances
2000	38 to 44	41 to 47
1800	39 to 45	42 to 48
1600	40 to 46	43 to 49
1400	41 to 47	44 to 50
1200	42 to 48	45 to 51
1000	43 to 49	46 to 52

**NOTE:** If a pressure decrease does not occur, either the hospital's supply pressure is too low or the regulator pressure is set too high.

# ( $\checkmark$ ) 6.14.3 O<sub>2</sub> Regulator

**NOTE:** Minimum cylinder pressure for  $O_2$  regulator test is 1000 psi.

- 6.14.3.1 Configure a test gauge (P/N 4114807) using an  $\rm O_2$  nut/stem DISS connector (P/N 4114830-006) on the hose and an  $\rm O_2$  DISS body connector (P/N 4114830-005) on the valve body side.
- 6.14.3.2 Connect the test fixture hose to the machine's oxygen pipeline inlet.
- 6.14.3.3 Connect the oxygen pipeline supply hose to the test fixture.
- 6.14.3.4 Set the oxygen flow to 4 L/min.
- 6.14.3.5 Depress the push button on the test device.
- 6.14.3.6 Release the push button. After the pressure decay stabilizes, is the regulator output within the tolerance given in the following table? \_\_\_(Y)

Cylinder Pressure psi	USA Compensated Regulator output tolerances	ISO Compensated Regulator output tolerances
2000	38 to 44	41 to 47
1800	39 to 45	42 to 48
1600	40 to 46	43 to 49
1400	41 to 47	44 to 50
1200	42 to 48	45 to 51
1000	43 to 49	46 to 52

**NOTE:** If a pressure decrease does not occur, either the hospital's supply pressure is too low or the regulator pressure is set too high.

# $(\checkmark)$ 6.15 Low O<sub>2</sub> Supply - Six month service interval

- 6.15.1 Close the oxygen cylinder valve and drain all oxygen pressure.
- 6.15.2 Depress the push button on the test device.
- 6.15.3 Adjust the Oxygen flow to 500 ml/min.
- 6.15.4 Release the test device push button.
- 6.15.5 When the LO  $O_2$  SUPPLY alarm activates, is the test pressure within 34 to 40 psi? \_\_\_(Y)

#### 6.16 Oxygen Supply Failure Protection

- 6.16.1 Connect all pipeline supplies.
- 6.16.2 Close the  $O_2$  flow control valve if applicable.
- ( $\checkmark$ ) 6.16.3 \*Is the flow of oxygen within 150 to 200 ml/min.? \_\_\_(Y)
  - 6.16.4 Open the  $N_2O$  flow control valve.
- ( $\checkmark$ ) 6.16.5 \*Is the flow of nitrous oxide within 375 to 750 ml/min.? \_\_\_(Y)
  - 6.16.6 Adjust the O<sub>2</sub>, N<sub>2</sub>O and Air flows to 4 L/min.
  - 6.16.7 Disconnect the  $O_2$  pipeline supply and close the  $O_2$  cylinder valve.

- ( $\checkmark$ ) 6.16.8 Do the N<sub>2</sub>O and Air flows cease when the O<sub>2</sub> pressure is depleted?
  - 6.16.9 Reconnect the  $O_2$  pipeline supply.
  - 6.16.10 Close the Air and  $N_2O$  cylinder valves, and disconnect the Air and  $N_2O$  pipeline supplies.
  - 6.16.11 Drain the residual pressure from the system.
  - 6.16.12 Close all flow control valves.

\*Nitrous Oxide bypass flow and Minimum Oxygen flow specifications are given @ 50 psi. Pipeline pressure deviations may affect these tests.

#### 6.17 Divan Operational Modes

- (✓) 6.17.1 Mechanical Ventilation
  - 6.17.1.1 Set the fresh gas flow to 3 L/min.
  - 6.17.1.2 Adjust the monitor's LO MIN VOL alarm to 2.0 liters.
  - 6.17.1.3 Set the Divan to Standby.
  - 6.17.1.4 Set Pmax to  $80 \text{ cm H}_2\text{O}$ .
  - 6.17.1.5 Set the Tidal Volume to 1000 ml.
  - 6.17.1.6 Set the Rate to 10/min.
  - 6.17.1.7 Set the %IP to 10.
  - 6.17.1.8 Connect a test lung to the Y-piece.
  - 6.17.1.9 Connect a test breathing bag to the bag arm.
  - 6.17.1.10 Remove the flow sensor from the test breathing circuit.
  - 6.17.1.11 Press the ventilator Volume Mode button and verify Volume Mode? text message is displayed, then press the confirm knob and start a stopwatch.
  - 6.17.1.12 Verify that the MIN VOL LOW message appears as a CAUTION.
- (✓) 6.17.1.13 Does the APNEA-VOL appear as a CAUTION alarm within 13 to 17 seconds? \_\_\_(Y)

<b>(√)</b>	6.17.1.14	Create a reverse flow by lightly blowing through the flow sensor in the reverse direction. Does the REVERSE FLOW message appear as an ADVISORY?(Y)
	6.17.1.15	Reattach the flow sensor to the Breasy and be certain to properly engage its anti-rotation bracket.
	6.17.1.16	S Install a 33mm x 22mm adapter (P/N 4115087) onto each volumeter port.
	6.17.1.17	Connect a 22mm x 32 inch hose (P/N 9995132) between the flow sensor and the connection at the bottom of the test volumeter.
	6.17.1.18	Attach the test patient circuit hose to the adapter at the top of the test volumeter.
<b>(√)</b>	6.17.1.19	Is the TID VOL on the test volumeter within 15% of the Divan Vt setting?(Y)
	6.17.1.20	Verify that the ventilator performs mechanical ventilation and does not make any scraping, humming or creaking noises. Refer to Troubleshooting Guide 14 for additional information.
	6.17.1.21	Observe the operation of each unidirectional valve disc at eye level and make sure that the inspiratory valve disc raises only during the inspiration phase, and the expiratory valve disc raises only during the exhalation phase. Both discs must move freely without sticking.
	6.17.1.22	Increase the PEEP to 20 cm ${ m H}_2{ m O}$ . Press the knob.
(✓)	6.17.1.23	Is the PEEP value displayed on the workstation monitor within 17 to 23 cm $H_2O$ ?(Y)
	6.17.1.24	Return the PEEP to 0 cm $\rm H_2O$ , then press the knob.
<b>(√)</b>	6.17.1.25	Is the PEEP value displayed on the workstation monitor within 0 to 2 cm $H_2O$ ?(Y)
	6.17.1.26	3 Press the SIMV button. Verify SIMV Mode? text message is displayed, then press knob to confirm.
	6.17.1.27	Press the SIMV Rate button and set SIMV Rate to 6/min.

Press the knob to confirm.

- 6.17.1.28 Before performing the next test, verify or install several strips of double-sided tape between both sides of the test lung case and its bag.
- 6.17.1.29 Start a stopwatch when inspiration begins.
- 6.17.1.30 After 8 seconds while watching the pressure waveform, grasp the test lung case and expand it to simulate a very shallow negative pressure trigger pulse.

**NOTE:** If unable to generate a trigger pulse, repeat the test and apply a less negative trigger pulse.

- $(\checkmark)$  6.17.1.31 Is a synchronized inspiration stroke triggered?
  - 6.17.1.32 Press the Pres Mode button. Verify Pressure Mode? Text message is displayed, then press knob to confirm.
  - 6.17.1.33 Press the Pset button and adjust parameter to 30 cm  $H_2O$ . Press the knob to confirm.
- ( $\checkmark$ ) 6.17.1.34 Is the PEAK pressure displayed on the workstation monitor within 27 to 33 cm  $H_2O?$  \_\_\_(Y)
  - 6.17.1.35 Verify that the ventilator continues to perform mechanical ventilation.
  - 6.17.1.36 Verify that the indicator in the upper left corner of the Press Mode button is now illuminated.
- (✓) 6.17.2 Manual/Spontaneous Ventilation
  - 6.17.2.1 Press the Manual/Spontaneous button. Verify the Manual/Spont? text message is displayed, then press the knob to confirm.
  - 6.17.2.2 Set the APL valve to SPONT and verify that spontaneous breathing can be implemented with the test lung.
  - 6.17.2.3 Set the APL valve to MAN.
  - 6.17.2.4 Verify that manual ventilation can be implemented with the test breathing bag.
  - 6.17.2.5 Connect a GAP Return adapter (P/N 4115040) to the Breasy's GAP exhaust return port. Connect a digital pressure meter to the GAP Return adapter.

- 6.17.2.6 Remove the test breathing bag and replace it with a squeeze bulb assembly.
- 6.17.2.7 Occlude the test breathing circuit Y-piece.
- 6.17.2.8 Set the APL control to MAN and adjust the scale to 70 cm  $\rm H_2O$ .
- 6.17.2.9 Set the fresh gas flow to 20 L/min.
- 6.17.2.10 Is the pressure within 56 and 84 cm  $H_2O$ ? \_\_\_(Y)
- 6.17.2.11 Set the APL control to MAN and adjust the scale to 30 cm  $\rm H_2O$ .
- 6.17.2.12 Is the pressure within 24 and 36 cm  $H_2O$ ? \_\_\_(Y)
- 6.17.2.13 If applicable, depress the Secondary Vacuum Relief Valve's plunger and verify that the NM6400 monitor pressure waveform immediately drops to zero.
- 6.17.2.14 Remove the test gauge and GAP Return adapter.
- 6.17.2.15 Close the oxygen flow control valves.
- 6.17.2.16 Press the ventilator Standby button. Verify Standby? text message is displayed, then press knob to confirm.

# 6.18 Open Reservoir Scavenger Pressure Relief - Six month service interval, if applicable

- 6.18.1 Activate the scavenger vacuum supply.
- 6.18.2 Turn the scavenger needle valve fully clockwise (closed).
- 6.18.3 Ensure that the unused scavenger port has the sealing plug in place.
- 6.18.4 Uncap the hose barb adapter at the rear of the scavenger and connect a digital pressure monitor to the hose barb on the adapter.
- 6.18.5 Set the oxygen flow on the anesthesia machine to 10 L/min.
- 6.18.6 Set the ventilator to Man/Spont mode and press the confirm knob.
- 6.18.7 Set the APL control to Spont.
- 6.18.8 The digital pressure gauge shall indicate a pressure of less than 1.0 cm  $H_2O$ .

- 6.18.9 Close all flow control valves on the anesthesia machine.
- 6.18.10 Adjust the scavenger needle valve until the flowmeter indicates between the white lines.
- 6.18.11 The digital pressure gauge shall indicate a pressure of 0 to -0.5 cm  $\rm H_2O$ .
- 6.18.12 Remove the test equipment, re-cap the scavenger adapter port and reconnect the scavenger hose.
- 6.18.13 Close the oxygen flow control valve.
- 6.18.14 Press the ventilator Standby key and press the confirm knob.

#### $(\checkmark)$ 6.19 A/C Scavenger Pressure Relief - Six month service interval, if applicable

- 6.19.1 Ensure that the unused scavenger port has the sealing plug in place.
- 6.19.2 Set the oxygen flow on the anesthesia machine to 10 L/min.
- 6.19.3 Set the ventilator to Man/Spont mode and press the confirm knob.
- 6.19.4 Set the APL control to Spont.
- 6.19.5 Connect a GAP Return adapter (P/N 4115040) to the Breasy's GAP exhaust return port. Connect a digital pressure meter to the GAP Return adapter.
- 6.19.6 Remove the hose from the bottom of the scavenger and occlude this port.
- 6.19.7 The digital pressure meter shall indicate a pressure of  $10.0 \text{ cm H}_2\text{O}$  or less.
- 6.19.8 Remove the test equipment and reconnect the scavenger hose.
- 6.19.9 Close the oxygen flow control valve.
- 6.19.10 Press the ventilator Standby key and press the confirm knob.

#### 6.20 Gas Analysis Pod (GAP), if applicable

**NOTE:** Before performing these tests, the GAP must be in the full accuracy mode. During normal operation a GAP will enter full accuracy mode within 20 minutes. However, because the GAP's  $\mathrm{CO}_2$  monitoring power-up default is in Standby mode, the unit will remain in hibernation and thus report Agent warm-up for longer than 20 minutes if it does not detect a  $\mathrm{CO}_2$  measurement. Applying verification gas, or breathing into the sample line will force a zero calibration and update the GAP's warm-up status.

#### 6.20.1 Sample Flow and Line Block

- 6.20.1.1 Examine the sample circuit consisting of the sample line, semi-permeable tube, filter, water trap container and if applicable the airway adapter. Replace any components as needed.
- 6.20.1.2 Connect the gas sample line to the Luer Lock fitting (P/N 4110709) at the top of the test flowmeter (P/N S000081).
- 6.20.1.3 Touch the  ${\rm CO_2}$  parameter box and adjust the slider bar to min flow.
- ( $\checkmark$ ) 6.20.1.4 Is the sample flow rate within 75 to 125 ml/min.? \_\_\_(Y)
  - 6.20.1.5 Touch the  ${\rm CO_2}$  parameter box and adjust the slider bar to max flow.
- ( $\checkmark$ ) 6.20.1.6 Is the sample flow rate within 175 to 225 ml/min.? \_\_\_(Y)
  - 6.20.1.7 Attach the hose at the lower port of the test flowmeter to the hose barb on the auxiliary O<sub>2</sub> flowmeter.
  - 6.20.1.8 Adjust the auxiliary  $O_2$  flowmeter flow control valve until the test flowmeter indicates 75 ml/min.
- (✓) Does a CO<sub>2</sub> LINE BLOCK alarm message appear on the monitor in approximately 15 seconds? \_\_\_(Y)
  - 6.20.1.10 Remove the test equipment, and close the auxiliary  ${\rm O}_2$  flow control valve.
  - 6.20.1.11 Verify that the LINE BLOCK message has cleared.

#### 6.20.2 Accuracy

6.20.2.1 Attach the  $\rm CO_2$  calibration adapter assembly (P/N 4110216) to the  $\rm CO_2$ /Agent calibration cylinder (P/N 4115863). Attach the sample line to the Luer connector on the cal adapter.

	6.20.2.2	Set the ${\rm CO_2}$ alarm status to Standby (gray shaded bell).
	6.20.2.3	Turn the flow control valve on the calibration adapter slightly counter-clockwise. $ \\$
(✓)	6.20.2.4	After one minute, is the MEAN ${\rm CO_2}$ value within 36 to 40 mm Hg?(Y)
(✓)	6.20.2.5	Is the MEAN $N_2O$ value within 57 to 63%?(Y)
<b>(✓)</b>	6.20.2.6	Is the MEAN DES value within 0.95 to 1.05%? $\_$ _(Y)
	6.20.2.7	Remove the sample line from the calibration adapter and start a stopwatch.
	6.20.2.8	Close the flow control valve on the calibration adapter and remove it from the cylinder.
(✓)	6.20.2.9	Does an APNEA-CO $_2$ alarm appear as a Caution within 27 to 33 seconds?(Y)
	6 20 2 10	Disable the $\mathrm{CO}_2$ alarm.
6.21 Gas A		od Two (GAP2), if applicable
0.2.	,	(c/, opp.::c
6.21.1	Sample	Flow & Line Block
	6.21.1.1	Examine the sample circuit of the sample line, semi- permeable tube, waterlok reservoir. Replace any components as needed.
	6.21.1.2	Connect the gas sample line to the Lucr Lock fitting (P/N $4110709$ ) at the top of the test flowmeter (P/N $S000081$ ).
	6.21.1.3	Touch the $\mathrm{CO}_2$ parameter box and set sample flow control to LOW.
<b>(✓)</b>	6.21.1.4	Is the sample flow rate within 40 to 80 ml/min.? $\underline{\hspace{1cm}}(Y)$
	6.21.1.5	Set the sample flow control to Normal.
<b>(✓)</b>	6.21.1.6	Is the sample flow rate within 170 to 230 ml/min.? $\_$ (Y)
	6.21.1.7	Attach the hose at the lower port of the test flowmeter to the hose barb on the auxiliary ${\rm O}_2$ flowmeter.
	6.21.1.8	Adjust the auxiliary $O_2$ flowmeter flow control valve until the test flowmeter indicates 75 ml/min.

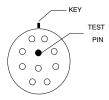
PMC PROCEDURE (continued)

<b>(√)</b>	(	6.21.1.9	Does a ${\rm CO_2}$ LINE BLOCK message appear on the monitor in approximately 15 seconds?(Y)
	6.21.2	Accurac	СУ
	(	6.21.2.1	Connect calibration adapter, (P/N 4110216) to the $\rm CO_2$ /Agent calibration gas canister (P/N 4107979-002). Attach the sample line to the Luer connect on the cal adapter.
	(	6.21.2.2	Set the ${\rm CO}_2$ status to Standby, (gray shaded bell).
	(	6.21.2.3	Turn the flow control valve on the calibration adapter slightly counter-clockwise.
<b>(√)</b>	(	6.21.2.4	After one minute, is the MEAN ${\rm CO_2}$ value within 36 to 40 mm Hg?(Y)
<b>(√)</b>	(	6.21.2.5	Is the MEAN $N_2O$ value within 67 to 73%?(Y)
<b>(√)</b>	(	6.21.2.6	Is the MEAN ISO agent value within 0.95 to 1.05%?(Y)
<b>(√)</b>	(	6.21.2.7	Is the MEAN SEV agent value within 0.95 to 1.05%?(Y)
	(	6.21.2.8	Remove the sample line from the calibration adapter and start a stopwatch.
	(		Close the flow control valve on the calibration adapter and remove it from the cylinder.
<b>(✓)</b>	(	6.21.2.10	Does an APNEA-CO $_2$ alarm appear as a Caution within 27 to 33 seconds?(Y)
	(	6.21.2.11	Disable the $CO_2$ alarm.
	6.22 Electric	al Safety	- One year service interval
<b>(√)</b>	6.22.1	Ground	Continuity
	(		Unplug the AC power cord for all devices mounted to the machine that may provide an alternate path to earth ground, such as a Desflurane vaporizer.
	(	6.22.1.2	Unplug the machine's AC power cord and plug the safety analyzer's power cord into this AC receptacle.
	]	NOTE: D	Oo not plug the safety analyzer power cord into a line isolation

monitor, as inaccurate readings may occur.

**NOTE:** The BIOTECH 501 PRO will automatically test the source outlet for open ground (or ground resistance of 31 ohms or higher), reverse polarity, open neutral and open line. (The latter two conditions will prevent the analyzer from powering up.)

- 6.22.1.3 Does the AC PWR FAIL message appear on the monitor?  $\underline{\hspace{1cm}}(Y)$
- 6.22.1.4 Turn on the safety analyzer and set its function switch to the GROUND WIRE RESISTANCE position. Attach the test lead to the red SINGLE LEAD connector of the analyzer. Connect the other end of the test lead to the AC receptacle ground socket on the analyzer. Verify a displayed resistance of 0.00 ohms. If necessary, press the CALIBRATE key on the front panel of the analyzer to zero the device.
- 6.22.1.5 Set the safety analyzer GROUND switch to the NORMAL position. Set the POLARITY switch to OFF.
- 6.22.1.6 Plug the NM6400 power cord into the safety analyzer.
- 6.22.1.7 Apply the analyzer's test lead to a cylinder bolt.
- 6.22.1.8 Is the value displayed on the safety analyzer within 0.0 to 0.1 Ohm?  $\_\_(Y)$
- $(\checkmark)$  6.22.2 Circuit Isolation
  - 6.22.2.1 Disconnect the respiratory volume sensor cord from the interface panel.
  - 6.22.2.2 Using a multimeter set to its highest resistance range, apply the test leads between the yoke bolt and the circuit common at the volume interface test pin as shown in the illustration. There shall be no continuity between these points.



6.22.2.3 Reconnect the respiratory volume sensor cord to the interface panel.

- 6.22.3 Chassis Leakage Current
  - 6.22.3.1 Set the safety analyzer to the Chassis Leakage Current position.
  - 6.22.3.2 Attach the safety analyzer test lead to a cylinder yoke.
- (✓) 6.22.3.3 Record the total leakage current with the polarity and ground switches set to the following positions:

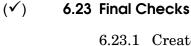
Ground Polarity
Normal Normal
Open Normal
Open Reversed
Normal Reversed

Verify that the leakage current is 100 microamps or less in each of the switch positions. (300 microamps if external monitors are plugged into convenience receptacles.)

- 6.22.3.4 Turn off and unplug the safety analyzer. Remove the anesthesia machine plug from the analyzer and plug it into the original AC receptacle.
- (✓) 6.22.4 Convenience Receptacle and Auxiliary Outlet Strip

**NOTE:** This test will check the convenience receptacle and auxiliary strip outlets for fault conditions such as open ground, reverse polarity, open line and open neutral.

- 6.22.4.1 Remove all devices from the convenience receptacle and the auxiliary strip outlets.
- 6.22.4.2 Plug the Receptacle Tester into the convenience receptacle. Verify no wiring fault is indicated, then remove the test plug and move it to the first auxiliary outlet. Repeat this process until the convenience receptacle and all auxiliary strip outlets are tested.
- 6.22.4.3 Reconnect the AC power cords to all devices mounted to the machine or previously removed from the convenience receptacle and the auxiliary strip outlets.



- 6.23.1 Create any Warning Alarm condition.
- 6.23.2 Press the ALARM SILENCE button in the alarm box.
- ( $\checkmark$ ) 6.23.3 Is the audio alarm silenced? \_\_\_(Y)
  - 6.23.4 Verify that a 60 appears at the bottom of the alarm box and begins to count down.
  - 6.23.5 Press the Setup key and select the Setup tab.
- (✓) 6.23.6 Press the Test Primary Speakers key. Does the primary speaker test pass? \_\_\_(Y)
- ( $\checkmark$ ) 6.23.7 Press the Test Backup Speaker key. Does the backup speaker test pass?  $\underline{\hspace{1cm}}$ (Y)
- (✓) 6.23.8 Press the Test Battery key. Is the battery fully charged? \_\_\_(Y)
  - 6.23.9 Press the Setup key to close the System Setup Notebook.
  - 6.23.10 Restore all connections to the patient interface panel.
  - 6.23.11 Verify that the pipeline hoses are connected to the hospital pipeline outlets.
  - 6.23.12 Remove the  $O_2$  sensor from the inspiratory valve dome and insert the plug into the dome.
  - 6.23.13 Set the APL valve to MAN. Remove the test volumeter; reattach the breathing bag and CO<sub>2</sub> sample line to the Y-piece.
- (✓)
  6.23.14 Press and hold the Divan TEST button for 3 seconds. Does the Divan complete a leak and compliance test and return to Standby, indicating that the test is successfully completed? \_\_\_(Y)
  - 6.23.15 Verify the correct date and time on the Narkomed 6400 main display screen.
  - 6.23.16 Verify that both table top lamps are functional.
  - 6.23.17 Verify that the flowmeter lights are illuminated and all flow control valves are closed.
- (✓)
  6.23.18 Is the machine's Operator's Instruction Manual (including Integrated Patient Monitor if applicable) is in close proximity of the machine?
  \_\_\_(Y)
  - 6.23.19 Press the Monitor Standby key and select YES to confirm.

#### 6A.0 Test Procedure for the Integrated Patient Monitor

The following pages contain the PMC procedures for the Integrated Patient Monitoring Module. The purpose of the PMC procedure is to provide service personnel with a method that can be used to verify operational and functional performance of the monitor. Failure to attain any of the listed results indicates a potential malfunction of the monitor.

The procedures in this section shall be performed in their entirety at initial installation, during all scheduled Periodic Maintenance Certification (PMC) visits, and each time an Integrated Patient Monitoring Module is removed, replaced, calibrated or adjusted. The exception to this requirement is the Integrated Patient Monitoring Module, (IPMM), installed on the Narkomed 6400. The Narkomed 6400 has been specifically designed to operate these assemblies as plug and play devices in the event of a failure during clinical use. Draeger Medical, Inc. recommends the following precautions:

- Spare IPMMs should be controlled carefully by the facility.
- Before replacing the IPMM, the clinician should verify that the
  replacement pod appears to be in good condition. If there is any doubt
  about the replacement pod's quality, the pod should not be used
  without first contacting an authorized representative of Drager
  Service.
- The clinician should perform a complete Narkomed 6000 Series selftest as soon as practical. Full system self-diagnostics will run at that time.

A PMC Checklist form, P/N 4116820, available from the Draeger Medical, Inc. Technical Service Department, shall be completed by the Technical Service Representative each time a PMC is performed. The section numbers on the checklist form are keyed to paragraph numbers in this manual. Steps in the procedure marked with  $(\checkmark)$  require a response at the corresponding line on the checklist form.

The PMC procedure is based on the assumption that the Integrated Patient Monitoring Module being tested is used with known good cables and test equipment. It also requires that the user be somewhat familiar with the operation of all test equipment required for the PMC procedure. For more information concerning operation of these components, refer to the respective operator manual.

INTEGRATED PATIENT MONITORING MODULE PMC PROCEDURE (continued)

NM6000 Series

#### Test Equipment Required:

Test equipment listed with an asterisk (\*) requires calibration at a maximum interval of one year. Verify the dates on test equipment calibration labels. DO NOT USE any test equipment having an expired calibration date. Notify your supervisor immediately if any equipment is found to be out of calibration.

In the space provided at the bottom of the checklist form, record the Model and ID number of all calibrated test equipment used.

The following table lists the test equipment, adapters, and cables necessary to successfully complete the PMC procedure. The PMC procedure was written for the test equipment in the following table. If test equipment other than the manufacturer's recommendation is used, it may be necessary to slightly modify some test steps.

INTEGRATED PATIENT MONITORING MODULE PMC PROCEDURE (continued)

MARQUETTE TEST EQUIPMENT for INTEGRATED PATIENT MONITORING MODULE						
Description Part # Qty Vendor Notes						
* Electrical Safety Analyzer, Biotek 501 Pro or equiv.		1	Biotek	Can also be obtained locally		
* Multifunction Patient Simulator Kit (see note below)	4117115	1	DMI	Marquette #MARQ II Kit		
* SPO2 Simulator	4117116	1	DMI	Marquette #408610-001		

MARQUETTE MATERIALS for INTEGRATED PATIENT MONITORING MODULE							
Description	Part #	Qty	Vendor	Notes			
ECG 5-Leadwire Set	4113274	1	DMI				
ECG Cable, 5-leadwire, AHA	4113273	1	DMI				
NIBP Adult Cuff	4113395-004	1	DMI				
NIBP Interface Cable	4113454	1	DMI				
NIBP Test Adapter	4116111	1	DMI				
SPO2 Finger Probe	4113823	1	DMI				
SPO2 Interface Cable	4113453	1	DMI				
Blood Pressure Cable Adapter (Amp to Nicolay) Pigtail	4117117	4	DMI	Marquette #700095-001			
Cardiac Output Cable Adapter (Amp to Nicolay) Pigtail	4117118	1	DMI	Marquette #700092-001			
Marq-II Blood Pressure Cable	4117119	4	DMI	Marquette #5183072			
Marq-II Carrying Case	4117120	1	DMI	Marquette #6770042			
Marq-II Temperature Cable Y.S.I. 400	4117121	2	DMI	Marquette #5183001			
SPO2 Adapter Cable	4117123	1	DMI	Marquette #700232			
Defib Sync Connector	4117114	1	DMI				

MARQUETTE TEST MATERIALS for STRIP CHART RECORDER						
Description Part # Qty Vendor Notes						
Chart Paper	4110335	1	DMI			

<sup>\*</sup> Requires calibration at a maximum interval of one year.

NOTE: Multifunction Patient Simulator kit includes:

1 ea Carrying case

1 ea Multifunction Simulator

1 ea Cardiac Output module

2 ea Blood Pressure cable

1 ea Temp cable: YSI 400 1 ea Temp cable: YSI 700

#### 6A.1 Electrical Safety Analysis

**NOTE:** Do not plug the safety analyzer power cord into a line isolation monitor, as inaccurate readings may occur.

#### 6A.1.1 Lead Isolation Factor:

- 6A.1.1.1 Disconnect the ECG cable from the Integrated Patient Monitoring Module interface.
- **NOTE:** Reference your Safety Analyzer operator manual for specific operations to perform these tests.
- 6A.1.1.2 Connect the power cord of the safety analyzer to an AC receptacle.
- 6A.1.1.3 Connect the power cord of the unit under test to the safety analyzer.
- 6A.1.1.4 Connect the ECG cable (P/N 4113273) to the 5-lead set (P/N 4113274) and connect the leads to the safety analyzer, but do not connect the cable to the Integrated Patient Monitoring Module.
- 6A.1.1.5 Set the safety analyzer Power Switch to ON. Turn the System Power switch to ON.
- 6A.1.1.6 Set the safety analyzer to measure ECG leakage current.
- 6A.1.1.7 Select for all leads to be tested (ALL GND).

CAUTION: During this testing, DO NOT touch the ECG posts.

- 6A.1.1.8 Press and hold the ISOLATION key.
- (✓) Record the reading from the display (referred to as the Lead Isolation Factor) on the test report.
  - 6A.1.1.10 Release the ISOLATION key.
  - 6A.1.2 Patient Source Leakage:

This test checks leakage current from the ECG connector of the monitor relative to ground.

6A.1.2.1 Connect the ECG cable to the ECG connector of the monitor.

(✓) 6A.1.2.2 Record the total leakage current with the Polarity and Ground switches set to the following positions:

GroundPolarityOpenNormalNormalNormalOpenReversedNormalReversed

Verify that the leakage current is 10 microamps or less in each of the switch positions.

# 6A.1.3 Patient Sink Leakage:

This tests patient cable leakage current from a 115 VAC source into the ECG connector of the monitor.

- 6A.1.3.1 Set power switch on the safety analyzer to ON.
- 6A.1.3.2 Set the safety analyzer switches as follows:
  - Ground switch NORM,
  - Polarity switch NORM,
  - Select ECG leakage (ALL GND).
- WARNING: The following step will cause high voltage (115 VAC) to appear at the ECG JACK on the safety analyzer. Do not touch the ECG Jack posts or ECG lead clips during this test as an electrical shock will occur.
- (\*) 6A.1.3.3 Press and hold the ISOLATION key. Read leakage current indicated on safety analyzer. Release the ISOLATION key. Subtract the lead isolation factor recorded earlier from this value.

If the sum of the readings is greater than 10  $\mu A$  and the monitor is operating at 115 V/60 Hz, the unit under test fails this test and should be repaired and tested again.

- 6A.1.3.4 Change the safety analyzer polarity switch to the REV POL position.
- (\*) 6A.1.3.5 Press and hold the ISOLATION key. Read leakage current indicated on safety analyzer. Release the ISOLATION key. Subtract the lead isolation factor recorded earlier from this value.

If the sum of the readings is greater than 10  $\mu A$  and the monitor is operating at 115 V/60 Hz, the unit under test fails this test and should be repaired and tested again.

- 6A.1.3.6 Set the power switch on the safety analyzer to OFF.
- 6A.1.3.7 Disconnect all test equipment from the Integrated Patient Monitoring Module. Disconnect the machine power cord plug from the safety analyzer power receptacle. Disconnect the safety analyzer from the wall receptacle. Plug the machine's power cord back into the machine.

#### 6A.2 ECG tests

Touch the Set Up key, select the Traces tab. Note the current selection for future reference. For software versions  $\leq 2.06$  select 8 WFs; 3 IBP channels; 5 Lead ECG. For software versions  $\geq 3.00$  select Automatic mode.

- **NOTE:** Cycle patient multi-parameter simulator (P/N 4117115) to restore unit to power up default values.
- 6A.2.1 Turn on the patient multi parameter simulator and enter Code "1" to select a normal sinus rhythm. Verify the simulator displays:
  - Heart rate 80 bpm,
  - Heart rate amplitude 1.0 mV,
- 6A.2.2 Connect the 5 ECG leads to the outside row of color coded terminals at the top of the simulator as follows: RA = wht, RL = grn, V1 = brn LA = blk, LL = red
- 6A.2.3 Connect the ECG cable to the Integrated Patient Monitoring Module interface.
  - If software version is  $\leq 2.06$ , touch the SpO2 window to open the SpO2 notebook. Toggle the SpO2 tone to Off, then close the SpO2 notebook.
- 6A.2.4 Touch the HR window to open the HR notebook. Select the Setup tab and toggle the QRS tones to ON. Select the Volume tab and adjust the arrow Up and Down keys on the Integrated Patient Monitoring Module interface to verify that the audio tone is adjustable. Move the slider and verify that the audio tone is adjustable. Return the slider tab to its midpoint.
- 6A.2.5 Select the Site Scale tab. Touch the ECG Channel #1 key. Select Lead II. Touch the Scale key and select 1.0x.
- (✓) 6A.2.6 Is ECG lead II displayed and noise free, with a heart rate of 75 to 85 bpm and an audible tone each R-wave (QRS complex)? \_\_\_(Y)

#### NM6000 Series INTEGRATED PATIENT MONITORING MODULE PMC PROCEDURE (continued)

**(√**) Verify Channel 1 I, II, III, aVR, aVL, aVF; Channel 2 I, II, III, V, aVR 6A.2.7ECG leads are available for viewing and are noise-free. Return lead selection to Lead II. **NOTE:** The same lead can not be used on both channels at the same time. 6A.2.8Touch the Scale key and toggle through all 5 scales. Verify they are available and increase or decrease the size of the waveform. Return the scale to 1.0x 6A.2.9 Touch the HR Alarms tab and note all HR alarm parameters. Toggle the Alarm control to ON. 6A.2.10 **(√**) 6A.2.11 Raise the Heart Rate Limit Set Lo alarm above the actual value. Verify HRT RATE LOW appears as a Warning. Readjust the alarm to below the actual value. The alarm shall cease. Return the alarm to its original position. **(√**) Lower the Heart Rate Set Hi below the actual value. Verify HRT 6A.2.12 RATE HI appears as a Caution. Readjust the alarm to above the actual value. The alarm shall cease. Return the alarm to its original position. **(√**) 6A.2.13 Enter Code "3" and use the simulator's increment key to adjust the simulator heart rate amplitude to 2.0 mV. Enter Code "110" to set the simulator's Pace to Asynchronous Pacemaker rate. NOTE: Touch the Relearn key if 'astol' is displayed. Touch the ECG setup tab and toggle the Pace Pulse to Normal. Observe the following while viewing ECG leads II, III, aVR, aVF, and • a **P** appears above to the right of the heart icon indicating pacemaker pulse detection is enabled, and • the heart rate still reads  $75 \pm 5$  bpm. 6A.2.14 Disable the monitor's pacemaker pulse detection and return the simulator to these conditions by entering Code "1" for NSR and Code "3" decrement to 1.0 mV. Verify the simulator displays: • Heart rate - 80 bpm, • Heart rate amplitude - 1.0 mV,

Select ECG lead II for viewing in the top trace position on the

6A.2.15

monitor display.

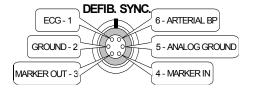
- 6A.2.16 Disconnect the RA leadwire from the patient simulator.
- (✓) 6A.2.17 Does ECG RA Disc alarm message appear on the display? \_\_\_(Y)
  - 6A.2.18 Reconnect the RA leadwire to the patient simulator, and the alarm shall cease.
- (\*) 6A.2.19 Touch the ECG Setup tab and touch the Relearn key. Does Relearn in Progress display for a short while, and then the heart rate information appear? \_\_\_(Y)

#### **6A.3 Battery Operation**

- 6A.3.1 Disconnect the system power cord plug from the wall receptacle.
- 6A.3.2 Verify the message AC POWER FAIL appears on the central monitor display. If the software version is ≥ 3.00, acknowledge the AC Power Fail Warning by pressing OK.
- 6A.3.3 Enter Code "1" on the patient simulator to select a normal sinus rhythm:
  - ECG heart rate 80 bpm,
  - ECG amplitude 1.0 mV,
- (✓) 6A.3.4 Is ECG lead II displayed and noise free, with a heart rate of 75 to 85 bpm and an audible tone each R-wave (QRS complex)? \_\_\_(Y)
  - 6A.3.5 Verify all seven ECG lead sites are selectable for display on the monitor and are noise free.
  - 6A.3.6 Connect the power cord plug to the wall receptacle.

#### 6A.4 Defibrillator Synchronization Tests

6A.4.1 Use the following figure as a reference for connecting the shunt to the DEFIB SYNC connector, located on the front panel of the monitor, for performing this test.

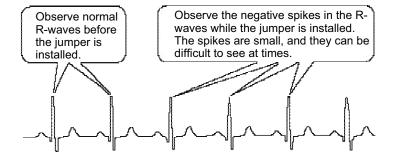


- 6A.4.2 Enter Code "1" on the Patient Simulator to select a normal sinus rhythm of:
  - ECG heart rate 80 BPM
  - ECG amplitude 1.0 mV

Defibrillator synchronization tests Verify markers

(\*)

6A.4.3 Attach a defib sync shunt connector jumper wire or defib sync connector (P/N 4117114) between pin-3 (Marker Out) and pin-4 tests (Marker In) of the DEFIB SYNC connector located on the front of the monitor. Verify white colored negative spikes in each of the QRS Complex (ECG waveform) R-Waves on the monitor display, similar to those shown in the illustration below.



Defibrillator synchronization tests completion:

6A.4.4 Remove the jumper wire or defib sync connector installed in the previous step, from the DEFIB SYNC connector. This completes the defibrillator synchronization tests.

# (✓) 6A.5 ST Segment Analysis

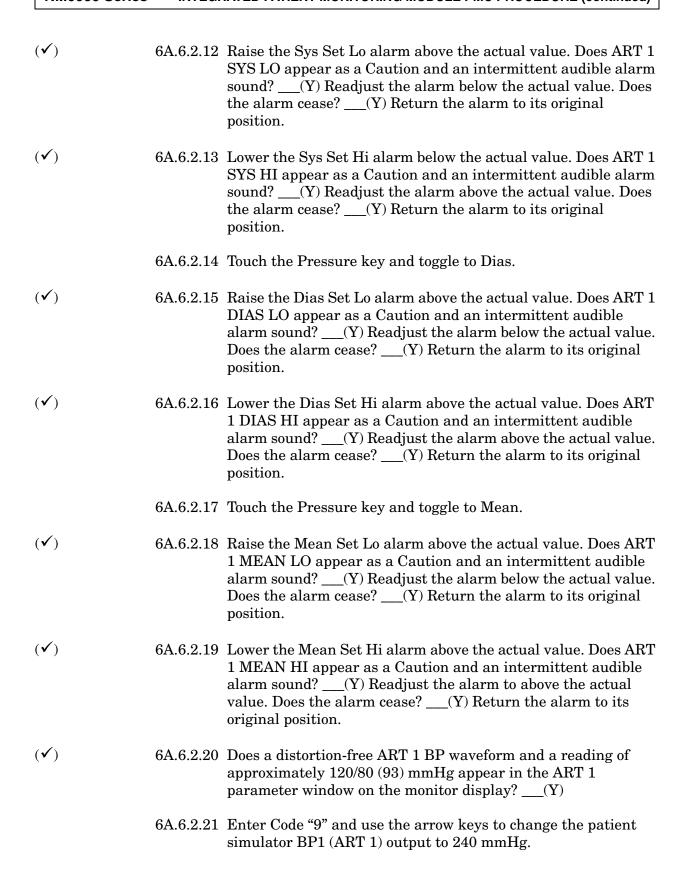
- 6A.5.1 Touch ST Segment to open the ST Segment window.
- 6A.5.2 Enter Code "145" and use the simulator's increment key to raise the ST Elevation to +0.1 mV. Does lead II indicate a positive value?
  \_\_\_(Y)
- 6A.5.3 Use the simulator's decrement key to lower the ST Depression to -0.1 mV. Does lead II indicate a negative value? \_\_\_(Y)
- 6A.5.4 Enter Code "1" on the Patient Simulator to select a normal sinus rhythm.

6A.5.5 Touch the ST Parameter box to close the ST Segment window.

#### 6A.6 Invasive Blood Pressure

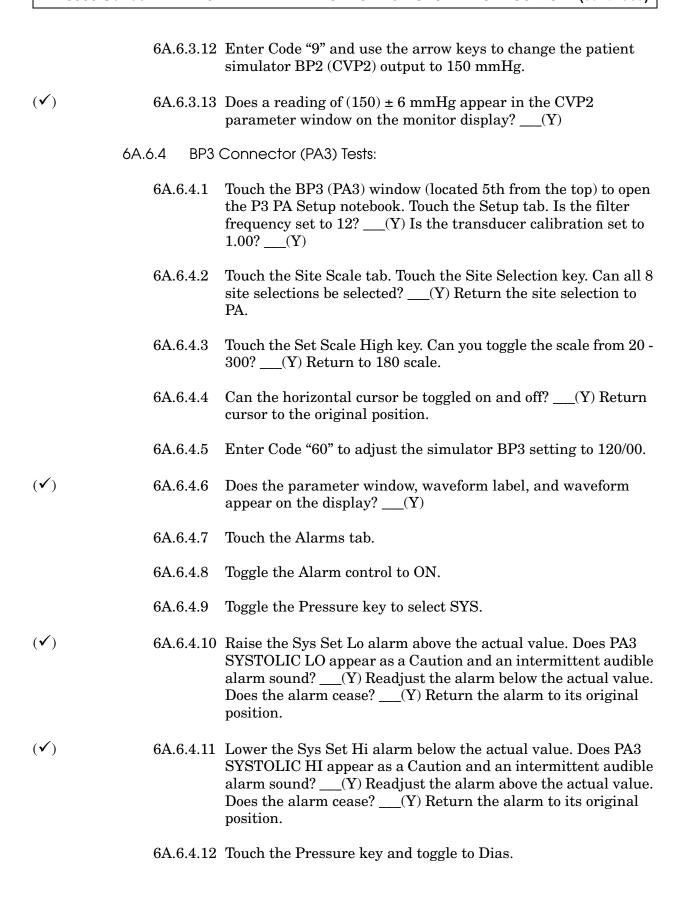
- **NOTE:** This monitor's invasive blood pressure sensitivity is calibrated to  $5\mu V/V1$  mmHg.
- 6A.6.1 Enter Code "132 to calibrate the simulator's invasive monitor sensitivity to 5μV/V1 mmHg.
- 6A.6.2 BP1 Connector (ART) Tests:
  - 6A.6.2.1 Connect the BP simulator cable (P/N 4117119) to BP cable adapter P/N 4117117) and connect the BP1 connector of the patient simulator to the BP1 connector of the Integrated Patient Monitoring Module. Repeat this procedure for BP2 and BP3. Also repeat this procedure for BP4 if software version is  $\geq 3.00$ .
  - 6A.6.2.2 Press the ZERO ALL push-button on the front panel of the monitor interface and verify a green LED illuminates for several seconds.
  - 6A.6.2.3 Touch the BP1 window (located 3nd from the top) to open the P1 notebook. Touch the Setup tab. Verify that the filter frequency is set to 12. Verify that transducer calibration is set to 1.00.
  - 6A.6.2.4 Touch the Site Scale tab. Touch the Site Selection key and verify all 8 site selections can be selected. Return the site selection to ART.
  - 6A.6.2.5 Touch the Set Scale High key. Verify that you can toggle 20 300. Return to 180 scale.
  - 6A.6.2.6 Can the horizontal cursor be toggled on and off? \_\_\_(Y) Return cursor to the original position.
  - 6A.6.2.7 Enter Code "60" to adjust the simulator BP1 setting to 120/80.
- (✓) 6A.6.2.8 Does the ART 1 parameter window, waveform label, and waveform appear on the display? \_\_\_(Y)
  - 6A.6.2.9 Touch the Alarms tab.
  - 6A.6.2.10 Toggle the Alarm control to ON.
  - 6A.6.2.11 Toggle the Pressure key to select SYS.

#### INTEGRATED PATIENT MONITORING MODULE PMC PROCEDURE (continued)

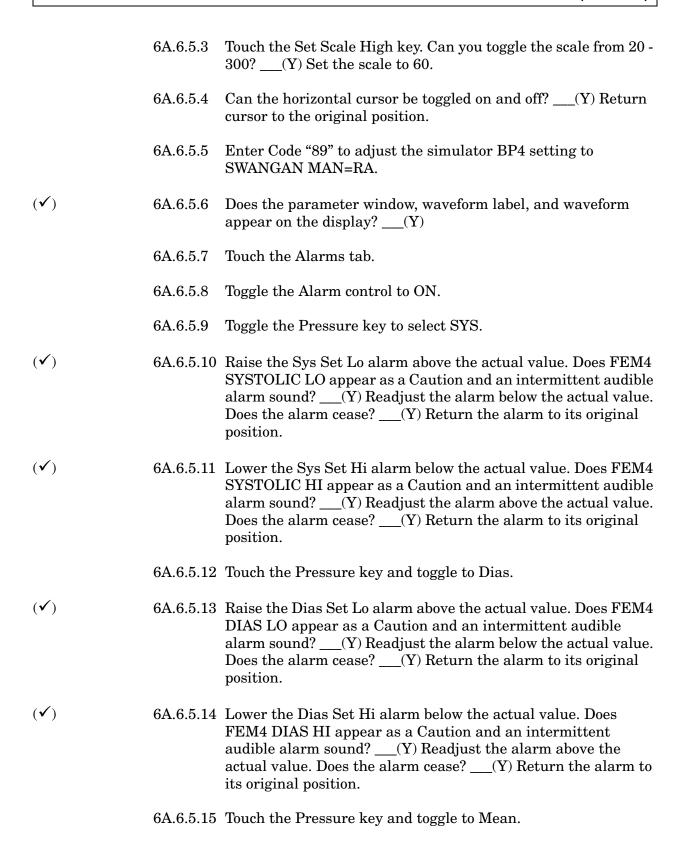


**(√**) 6A.6.2.22 Does a reading of 240/240 (240) ± 10 mmHg appear in the ART 1 parameter window on the monitor display? \_\_\_(Y) NOTE: With software version  $\leq 2.06$ , BP2 and BP3 are only available on 8 waveform display. BP4 is not used. With software version  $\geq 3.00$  IBP cables must be connected before corresponding IBP parameter box appears. 6A.6.3 BP2 Connector (CVP2) Tests: 6A.6.3.1 Touch the BP2 (CVP2) window (located 4th from the top) to open the P2 CVP Setup notebook. Touch the Setup tab. Is the filter frequency set to 12? \_\_\_(Y) Is the transducer calibration is set to 1.00? \_\_\_(Y) 6A.6.3.2 Touch the Site Scale tab. Touch the Site Selection key. Can all 8 site selections be selected? \_\_\_(Y) Return the site selection to CVP. Touch the Set Scale High key. Can you toggle the scale from 20 -6A.6.3.3300? (Y) Return to 30 scale. 6A.6.3.4 Can the horizontal cursor can be toggled on and off? \_\_\_(Y) Return cursor to the original position. Enter Code "60" to adjust the simulator CVP2 setting to 25/10. 6A.6.3.5**(√**) 6A.6.3.6 Does CVP2 parameter window, waveform label, and waveform appear on the display?  $\underline{\hspace{1cm}}(Y)$ 6A.6.3.7 Touch the Alarms tab. 6A.6.3.8 Toggle the Alarm control to ON. **(√**) 6A.6.3.9 Raise the Mean Set Lo alarm above the actual value. Does CVP2 MEAN LO appear as a Caution and an intermittent audible alarm sound? (Y) Readjust the alarm below the actual value. Does the alarm cease? (Y) Return the alarm to its original position. **(√)** 6A.6.3.10 Lower the Mean Set Hi alarm above the actual value. Does CVP2 MEAN HI appear as a Caution and an intermittent audible alarm sound? \_\_\_(Y) Readjust the alarm above the actual value. Does the alarm cease? \_\_\_(Y) Return the alarm to its original position. **(√**) 6A.6.3.11 Does a distortion-free CVP2 BP waveform and a reading of approximately (15) mmHg appear in the CVP2 parameter

window on the monitor display? \_\_\_(Y)



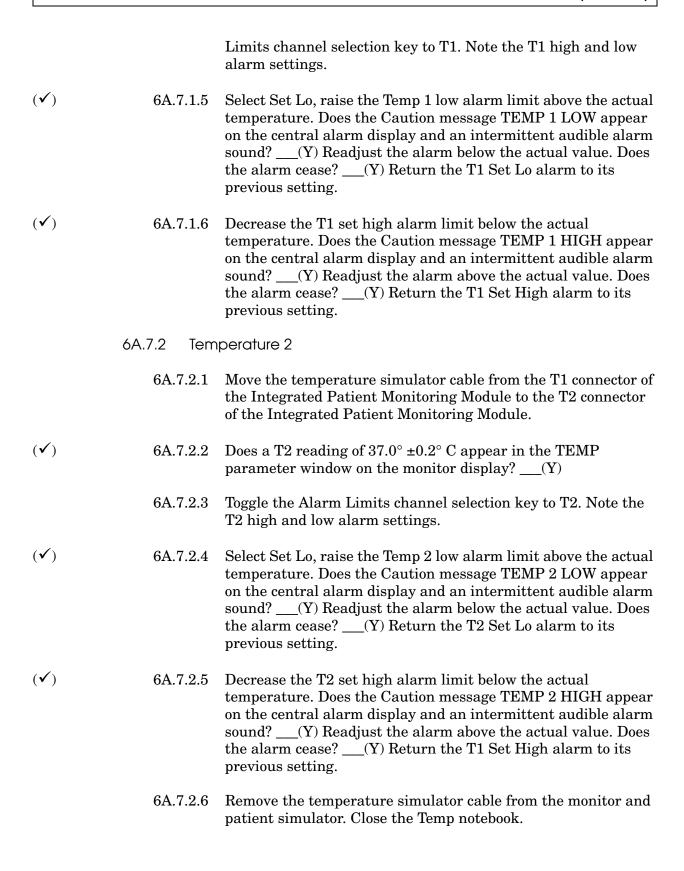
**(√**) 6A.6.4.13 Raise the Dias Set Lo alarm above the actual value. Does PA3 DIAS LO appear as a Caution and an intermittent audible alarm sound? \_\_\_(Y) Readjust the alarm below the actual value. Does the alarm cease? \_\_\_(Y) Return the alarm to its original position. **(✓**) 6A.6.4.14 Lower the Dias Set Hi alarm above the actual value. Does PA3 DIAS HI appear as a Caution and an intermittent audible alarm sound? \_\_\_(Y) Readjust the alarm above the actual value. Does the alarm cease? (Y) Return the alarm to its original position. 6A.6.4.15 Touch the Pressure key and toggle to Mean. **(√**) 6A.6.4.16 Raise the Mean Set Lo alarm above the actual value. Does PA3 MEAN LO appear as a Caution and an intermittent audible alarm sound? \_\_\_(Y) Readjust the alarm below the actual value. Does the alarm cease? \_\_\_(Y) Return the alarm to its original position. **(√**) 6A.6.4.17 Lower the Mean Set Hi alarm above the actual value. Does PA3 MEAN HI appear as a Caution and an intermittent audible alarm sound? (Y) Readjust the alarm above the actual value. Does the alarm cease? \_\_\_(Y) Return the alarm to its original position. **(✓**) 6A.6.4.18 Does a distortion-free PA3 BP waveform and a reading of approximately 120/00 (60) mmHg appear in the PA3 parameter window on the monitor display? \_\_\_(Y) 6A.6.4.19 Enter Code "9" and use the arrow keys to change the patient simulator BP3 (PA3) output to 60 mmHg. **(√**) 6A.6.4.20 Does a reading of 60/60 (60)  $\pm 3$  mmHg appear in the PA3 parameter window on the monitor display? \_\_\_(Y) 6A.6.5 BP4 Connector (FEM4) Tests, if applicable Touch the BP4 (FEM4) window (located 6th from the top) to 6A.6.5.1open the P4 FEM Setup notebook. Touch the Setup tab. Is the filter frequency set to 12? \_\_\_(Y) Is the transducer calibration set to 1.00? \_\_\_(Y) Touch the Site Scale tab. Touch the Site Selection key. Can all 8 6A.6.5.2site selections be selected? \_\_\_(Y) Return the site selection to FEM.



**(√**) 6A.6.5.16 Raise the Mean Set Lo alarm above the actual value. Does FEM4 MEAN LO appear as a Caution and an intermittent audible alarm sound? \_\_\_(Y) Readjust the alarm below the actual value. Does the alarm cease? \_\_\_(Y) Return the alarm to its original position. **(✓**) 6A.6.5.17 Lower the Mean Set Hi alarm above the actual value. Does FEM4 MEAN HI appear as a Caution and an intermittent audible alarm sound? \_\_\_(Y) Readjust the alarm above the actual value. Does the alarm cease? (Y) Return the alarm to its original position. **(√)** 6A.6.5.18 Does a distortion-free PA4 BP waveform and a reading of approximately 15/10 (12) mmHg appear in the FEM4 parameter window on the monitor display? \_\_\_(Y) 6A.6.5.19 Enter Code "9" and use the arrow keys to change the patient simulator BP3 (PA3) output to 60 mmHg. Channel P4 values are equal to P3 values. NOTE: **(√**) 6A.6.5.20 Does a reading of 60/60 (60)  $\pm 3$  mmHg appear in the FEM4 parameter window on the monitor display? (Y) 6A.7 **Temperature Tests: NOTE:** Accuracy for temperature simulation is valid only when the ambient operating temperature is in the 65 to 75° F range. 6A.7.1 Temperature 1 6A.7.1.1 Enter Code 191 to adjust simulator for a temperature output of 37°C. 6A.7.1.2 Attach the 400 series temperature adaptor cable (Draeger P/N 4117121) (Marquette P/N 5183001) to the C.O./Temp port of the simulator and connect the other end to the T1 connector of the Integrated Patient Monitoring Module. **NOTE:** Do not use 700 series temp adapter cable (Draeger P/N 4117122) (Marquette P/N 5183002) for testing. **(√**) 6A.7.1.3 Does a TEMP parameter window appear on the monitor display with a T1 reading of  $37.0^{\circ} \pm 0.2^{\circ}$  C? \_\_\_(Y)

Touch the Temp window to open the Temp notebook. Touch the Alarms tab. Toggle the Alarm control to ON. Toggle the Alarm

6A.7.1.4

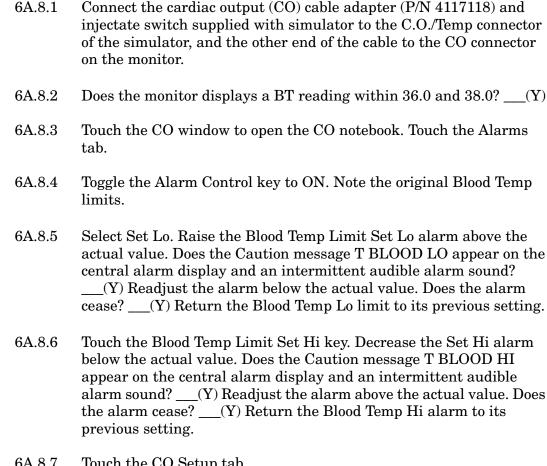


#### 6A.8 Cardiac Output Tests:

**(√**)

**(√**)

**(√**)



6A.8.7 Touch the CO Setup tab.

(✓)

6A.8.8 Toggle the CO simulator injectate temperature (IT) switch to 0.0°C.

Wait for the INJECT WHEN READY message to appear on the bottom of the Setup notebook. Enter Code "92" on the simulator.

After computing is complete, is the value within an acceptable range?

\_\_(Y) Toggle IT switch to 24.0°C. Wait for the INJECT WHEN READY message to appear on the bottom of the screen. Enter Code "95" on the simulator. After computing is complete, is the value within an acceptable range? \_\_(Y)

#### Simulator IT Setting Monitor IT Reading Range

0.0°C -0.3 - +0.3 24.0°C 22.8 - 25.2

6A.8.9 Disconnect the CO cable adaptor from the C.O./TEMP connector of the monitor. Close the CO notebook.

#### 6A.9 SPO2 / PULSE

Touch Setup Enable SpO2 tone.

- 6A.9.1 If necessary, connect the SpO2 adapter cable (P/N 4117123) to the marquette pulse oximetry simulator (P/N 4117116).
- 6A.9.2 Connect the SpO2 adapter to the Integrated Patient Monitoring Module interface.
- 6A.9.3 Toggle the OHMEDA/NELLCOR selector switch to NELLCOR, and turn on the simulator.
- (\*) 6A.9.4 Adjust the simulator pulse rate knob to 160 B/M. Using the white scale, adjust the simulator SpO2 to 99%. Does the monitor display a value within 96 and 100 for oxygen saturation, and a value within 155 and 165 for a pulse rate? \_\_\_(Y)
- (\*) Adjust the simulator pulse rate knob to 70 B/M. Adjust the simulator SpO2 knob to 68.4%. Does the monitor display a value within 66 and 71 for oxygen saturation, and a value within 68 and 72 for a pulse rate? \_\_\_(Y)
- (✓) Adjust the simulator pulse knob to 100 B/M. Adjust the simulator SpO2 knob to 80.3%. Does the monitor display a value within 77 and 83 for oxygen saturation, and a value within 97 and 103 for a pulse rate? \_\_\_(Y)
  - 6A.9.7 Touch on the SpO2 window background to open the SpO2 notebook. Touch the Setup tab and toggle NIBP interlock and SpO2 Tone to ON. Touch the Volume tab. Is the slider bar adjustable? \_\_\_(Y) Return the slider to the mid range position. Does an audible SpO2 tone sound with each pulse? \_\_\_(Y)
  - 6A.9.8 Select Alarms tab. Touch the Alarm Control toggle to ON, select Pulse channel. Note the pulse high and low alarm limit settings.
- (🗸)

  Select Set LO, raise the pulse low alarm limit above the actual pulse rate. Does the Warning message "OXI PULSE LOW" appear on the central alarm display and a continuous audible alarm sound? \_\_\_(Y)

  Readjust the alarm below the actual value. Does the alarm cease?
  \_\_\_(Y) Return the pulse low alarm limit to its previous setting.
- (✓)

  6A.9.10 Decrease the pulse high alarm limit below the actual pulse rate. Does the Caution message "OXI PULSE HIGH" appear on the central alarm display and an intermittent audible alarm sound? \_\_\_(Y)

  Readjust the alarm above the actual value. Does the alarm cease?
  \_\_\_(Y) Return the pulse high alarm limit to its previous setting.

- 6A.9.11 Select SpO2 channel. Note the SpO2 high and low alarm settings.
- (✓)

  6A.9.12 Select Set LO, raise the SpO2 low alarm limit above the actual SpO2 value. Does the Warning message "SPO2 LO" appear on the central alarm display and a continuous audible alarm sound? \_\_\_(Y)

  Decrease the SpO2 alarm limit below the actual SpO2 value. Does the alarm cease? \_\_\_(Y) Return the SpO2 low alarm limit to its previous setting.
- (🗸)

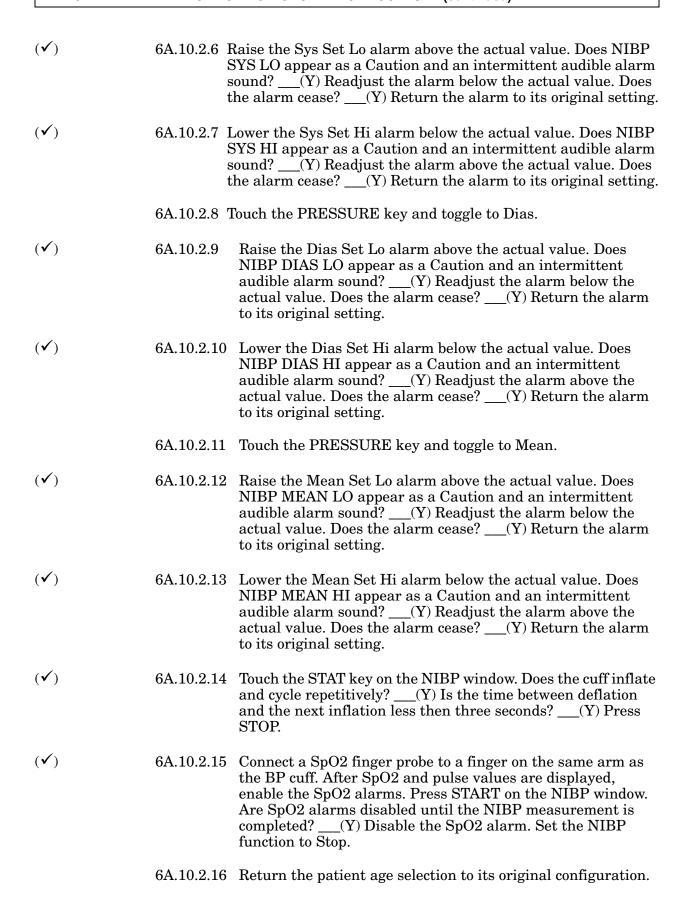
  6A.9.13 Decrease the SpO2 high alarm limit below the actual SpO2 value.

  Does the Caution message "SPO2 HI" appear on the central alarm display and an intermittent audible alarm sound? \_\_\_(Y) Raise the SpO2 Hi alarm limit above the actual SpO2 value. Does the alarm cease? \_\_\_(Y) Return the SpO2 high alarm limit to its previous setting.
  - 6A.9.14 Disconnect the pulse oximetry simulator from the Integrated Patient Monitoring Module interface. Turn the simulator power switch to the OFF position.
  - 6A.9.15 Connect the SpO2 interface cable (P/N 4113453) to the Integrated Patient Monitoring Module interface. Connect a finger probe (P/N 4113823) to the interface cable.
  - 6A.9.16 Attach the sensor to the operator's finger and obtain a pulse and oxygen saturation.
  - 6A.9.17 If either pulse or SpO2 alarms appear, readjust the alarm limits accordingly.
  - 6A.9.18 Disconnect the sensor from the finger.
- (✓) 6A.9.19 Within ten seconds, does the Warning message NO OXI PULSE appear on the central alarm display and a continuous audible alarm sound? \_\_\_(Y)
  - 6A.9.20 Touch the SpO2/Pulse bell to disable the alarm.

#### **6A.10 NIBP**

- (✓) 6A.10.1 NIBP Calibration
  - 6A.10.1.1 Access the NIBP Notebook setup page and set patient age to adult mode.
  - 6A.10.1.2 Access Service mode, select Service Monitors notebook, select CVP or IPMM tab.

- 6A.10.1.3 Remove the NIBP cable from the Integrated Patient Monitoring Module interface panel.
- 6A.10.1.4 Press the NIBP ZERO CALIBRATE key. NIBP Zero Cal in Progress will be displayed at the bottom of the notebook page. Wait until calibration is complete.
- 6A.10.1.5 Connect NIBP test cable (P/N 4113454) to the Integrated Patient Monitoring Module interface panel. Insert the NIBP test adapter (P/N 4116111) in line between either of the adult cuff (P/N 4113395-001) tubes and the corresponding interface tube. Connect a calibrated PDM to the NIBP test adapter. Wrap the adult cuff around an appropriately sized solid cylindrical object.
- 6A.10.1.6 Press the NIBP GAIN CALIBRATE key. This button label will change to SET CAL PRESSURE TO XXX. When the pressure stabilizes, use the arrow keys to adjust this value 1 mmHg below current manometer reading.
- 6A.10.1.7 When pressure reaches the selected value, press the SET CAL PRESSURE XXX key.
- 6A.10.1.8 Press the NIBP CHECK CALIBRATE key.
- 6A.10.1.9 Observe NIBP pressure value displayed at the lower right corner of the screen. Press the NIBP STOP CALIBRATE key when pressure values on the monitor equal the value on the meter ±1 mmHg for one minute.
- 6A.10.1.10Remove the test equipment; re-configure the cuff onto the interface hose, and exit the Service Menu.
- 6A.10.2 NIBP Verification
  - 6A.10.2.1 Install the BP cuff on your arm.
  - 6A.10.2.2 Touch the NIBP window to open the NIBP notebook.
  - 6A.10.2.3 Select the Set Up tab.
  - 6A.10.2.4 Adjust the Auto Interval slider bar to 5 min., set Patient Age to Adult.
  - 6A.10.2.5 Touch the START key on the NIBP window. When the BP measurement cycle is complete, touch the Alarms tab, and note all NIBP parameters. Toggle the alarm control to ON, toggle the Alarm Limits PRESSURE key to Select Sys.



# (✓) 6A.11 Strip Chart Recorder Assembly

- 6A.11.1 Touch the Print Key icon or the To Primary Keys icon. Then touch the Print icon to open the Printer notebook.
- 6A.11.2 Touch the Select Wave tab. Touch the SELECT WAVEFORM 1 key. Select any item found in the drop down list that has available data. Repeat this step for Waveform 2.
- 6A.11.3 Touch the Options tab. Open the printer door and remove the paper roll. Is the Door Open message displayed in the Print Options notebook? (Y)
- 6A.11.4 Close the printer door. Touch Quick Waveform Print (30 sec). Is the Paper Out message displayed in the Alarms window and the Print Options notebook? \_\_\_(Y)
- 6A.11.5 Open the printer door and insert paper (use test paper P/N 4110335 if needed) into the printer. Close the printer door.
- **NOTE:** Loose end of roll should be at the bottom of roll.
- 6A.11.6 Touch the Quick Waveform Print key, then press the Stop Print key. Is each data waveform recorded on the printout? (Y)
- 6A.11.7 Touch the Print Vital Signs key. Is all available data recorded on the print out? \_\_\_(Y)
- 6A.11.8 Touch the Print Data Log key, then press the Stop Print key. Touch the Data Log key. Does the information in the data log agree with the print out? (Y) Touch the Data Log key to close the data log.
- 6A.11.9 Touch the Start Continuous Waveform Print key. Is it functional?
  \_\_\_(Y) Touch the Stop Print key.

# (✓) 6A.12 Final IPMM and Strip Chart Recorder Checks

- 6A.12.1 Remove all test equipment; return all cables, hoses and accessories to their original configuration. Turn the MARQ-11 simulator to the OFF position.
- 6A.12.2 Touch the Set Up key and select the Traces tab. Return the number of screen traces to the original configuration.

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